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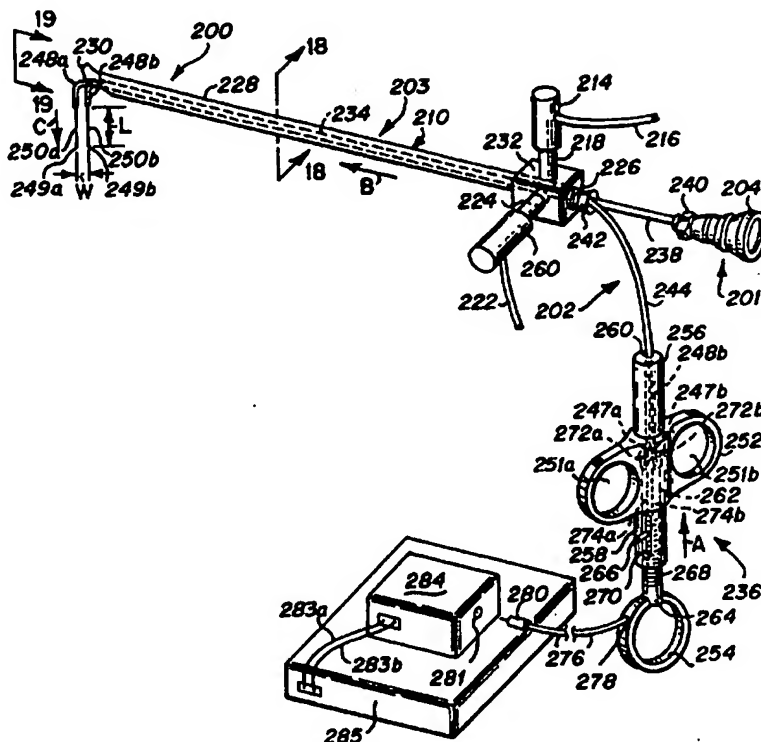
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(54) Title: ENDOSCOPIC SURGICAL INSTRUMENT

(57) Abstract

An improved electrode apparatus (202) for use with an endoscopic surgical instrument (200) provides an adjustable volume of tissue ablation, and may be used with an RF energy source (285) in either monopolar or bipolar output mode. The electrode apparatus (202) may be used in any endoscopic surgical application, and provides a new method for any endoscopic treatment involving soft tissue ablation, including hysteroscopic and laparoscopic treatment of uterine fibroids/myomas.



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1 Specification  
2 ENDOSCOPIC SURGICAL INSTRUMENT  
3

4 RELATED CASES

5 This application is a continuation-in-part of my co-  
6 pending U.S. Patent Application serial No. 08/025,003, filed  
7 March 2, 1993 which is a continuation-in-part of my co-pending  
8 U.S. Patent Application Serial No. 07/779,108 filed October  
9 18, 1991.

10

11 BACKGROUND OF THE INVENTION

12 Field of the Invention

13 This invention relates to a surgical instrument and more  
14 particularly to an instrument with the capability for  
15 continuous irrigation and evacuation of fluid into and out  
16 from a body cavity of a patient during Laparoscopic or  
17 Endoscopic surgical procedures, and for the simultaneous  
18 measurement of tissue impedance and the ablation of tissue  
19 with fixed or retractable electrodes using R.F. energy.

20

21 Brief Description of the Prior Art

22 Laparoscopic/endoscopic surgical procedure allows a  
23 surgeon to see inside the body cavity of a patient without the  
24 necessity of large incisions. This reduces the chances of  
25 infection and other complications related to large incisions.  
26 The endoscope further allows the surgeon to manipulate  
27 microsurgical instruments without impeding the surgeon's view  
28 of the area under consideration.

29 During these surgical procedures it is desirable for as  
30 few lines as possible to enter the body of the patient. This  
31 reduces the size of the incision the surgeon needs to make.  
32 It follows from this that the greater the number of functions  
33 provided by a single instrument or the greater the number of  
34 instruments able to be passed through a single line entering  
35 the patient's body, the better.

36 Furthermore, in certain procedures it may be desirable  
37 to irrigate the area under consideration. This in turn  
38 necessitates the evacuation of the irrigation fluid or, when

1   bleeding has occurred, the blood or smoke or tissue residue  
2   generated by the surgical procedure.

3       From what has been said above it should be apparent that  
4   it is preferable for both irrigation and evacuation to be  
5   conducted along a single conduit which, also, acts as an  
6   access line for surgical instruments.

7       A typical device which is used in endoscopic procedures  
8   is an electrosurgical probe. Typically such a probe will  
9   comprise a radio frequency (i.e. R.F.) energy conductive tube  
10   covered with a dielectric material such as polyolefin or  
11   Teflon. At one end, for convenience called the operational  
12   end, each probe could have any one of a number of functionally  
13   shaped monopolar or bipolar electrodes. In addition a probe  
14   could have its end formed specifically for irrigation and/or  
15   evacuation.

16       Monopolar and bipolar electrode probes are known in the  
17   prior art. Monopolar electrode probes include a single active  
18   electrode which is surgically introduced into a body cavity  
19   and engagable with and insertable into a tissue portion of the  
20   cavity. A passive electrode is attached to the outer body  
21   surface of the patient, e.g. typically a conducting plate is  
22   adhesively attached to the patient's leg. The body of the  
23   patient serves to complete the electrical circuit. Tissue  
24   ablation and coagulation is achieved by introducing sufficient  
25   power into the active electrode. Bipolar electrode probes  
26   include both active and passive electrodes which are similarly  
27   introduced together into the body cavity and are spaced apart  
28   from each other by a predetermined distance. Each electrode  
29   is engageable with and insertable into the tissue portion.  
30   Thus, the electrical circuit is completed by the body tissue  
31   disposed between the active and the passive electrodes and  
32   only the body tissue disposed between the two electrodes get  
33   coagulated.

34       Furthermore, any valves controlling the evacuation and  
35   irrigation procedures should be constructed so as to minimize  
36   the possibility of the valve malfunctions if, for example, any  
37   tissue or blood coagulates around their moving parts.  
38   Similarly if any of the instrumentation is to be reusable,

1 such instrumentation, including the valves, should be capable  
2 of being efficiently cleaned by, for example, flushing.

3 United States Patent 4,668,215 (Allgood) discloses a  
4 valve for switching between an evacuation and an irrigation  
5 conduit and allowing both such evacuation and irrigation to  
6 be done via a single line entering the patient. The mechanism  
7 for switching between the irrigation, evacuation and closed  
8 configurations is by means of a L-valve or T-valve. This  
9 patent, in another embodiment thereof, further provides for  
10 a piston valve for making an on-off connection between an  
11 evacuation port and the line leading into the patient.

12 The L- and T-valves have the disadvantage that they must  
13 be manipulated by rotation by the surgeon, usually using  
14 his/her free hand. The piston valve disclosed in this patent  
15 has the disadvantage that it has many areas where blood and  
16 tissue accumulation and coagulation can occur which may result  
17 in the malfunctioning of the valve. In addition, the piston  
18 valve has numerous "dead" areas where fluid flow would not  
19 occur. This precludes the device from being effectively  
20 cleaned by commonly used flushing techniques. Finally, the  
21 Allgood patent does not disclose a single body for housing an  
22 evacuation/irrigation control valve together with a housing  
23 for laparoscopic and microsurgical instrumentation.

24 A surgical valve that the applicant is aware of is the  
25 piston valve illustrated in Fig. 1 of the accompanying  
26 drawings.

27 In this valve a piston 10 is located within a cylinder  
28 11. The piston 10 can be moved along the bore of the cylinder  
29 11 by means of a plunger 12, from a closed position (as shown)  
30 to an open position in which a conduit 13 is aligned with an  
31 access port 14. This allows fluid flow along a path to or  
32 from access port 14, via conduit 13 and space 16 from or to  
33 a further port 15. Upon release of the plunger 12 the piston  
34 10 returns to its closed position under action of a spring 17.

35 This valve, although easy to use, has the disadvantage  
36 that blood and tissue accumulation occurs in space 16 and  
37 clogs both the space and the spring 17. This may result in

1 undesirable over-evacuation or irrigation of the patient  
2 during surgical procedures.

3

4

#### OBJECTS OF THE INVENTION

5 It is therefore an object of this invention to provide  
6 a surgical instrument which includes control means to allow  
7 for the continuous irrigation and evacuation of a body cavity  
8 of a patient during microsurgical procedures, with both  
9 irrigation and evacuation being performed along a single line  
10 into the patient. The instrument should also act as a  
11 mounting for electrosurgical probes and microsurgical  
12 instruments.

13 A further object of the invention is to provide a  
14 configuration for an instrument which, depending on the  
15 material it is constructed of, can be both disposable and non-  
16 disposable. In the event that the instrument is "reusable"  
17 or "reposable" it is an object of the invention to provide the  
18 instrument with conduits, access ports and valves which can  
19 easily be cleaned by means of commonly used cleaning  
20 techniques and conventional sterilization methods.

21 It is another object of the invention to provide an  
22 electrosurgical instrument with fixed or retractable RF  
23 electrodes having the capability to simultaneously perform  
24 controlled ablation of tissue using monopolar/bipolar R.F.  
25 energy and precise measurement of tissue impedance.

26 An object of the present invention is to provide an  
27 adjustable area of tissue coagulation, which may be larger or  
28 smaller than the size of the probe enclosing the electrodes.  
29 A further object is to provide multiple bipolar electrodes to  
30 allow a larger zone of coagulation. The spacing of the  
31 multiple electrodes may be adjusted for larger or smaller  
32 coagulation zones.

33 Another object of the present invention is to provide a  
34 single connecting cable system for use with an RF energy  
35 source and an RF electrode means whereby either the monopolar  
36 or bipolar output mode from the energy source may be selected  
37 and used with a single RF electrode means. The connecting  
38 cable system permits use of the single electrode means for

1 either RF output mode (monopolar or bipolar, which are  
2 typically labelled CUT and COAG, respectively on commercially  
3 available RF generators), and the user may elect the output  
4 mode while the electrode means are in situ.

5 Still another object of the invention is to provide a  
6 method for hysteroscopic and laparoscopic treatment of uterine  
7 fibroids/myomas with monopolar or bipolar electrosurgical  
8 instrumentation for controlled ablation of tissue.

9

10

1                                    SUMMARY OF THE INVENTION

2            According to this invention, an endoscopic surgical  
3    instrument comprises an irrigation and an evacuation port,  
4    each port being connected through independent valves to a  
5    single access conduit; a probe connector located at one end  
6    of the access conduit, the probe connector being for receiving  
7    and retaining a hollow surgical probe; and a monopolar or  
8    bipolar radio frequency connector which exits into the access  
9    conduit in such a manner so as to make radio frequency  
10   connection with a probe received by the probe connector.

11           Preferably the connector for receiving an end, for  
12   convenience called the locating end, of the probe would be in  
13   the form of a receiving bore in the access conduit which would  
14   include a plurality of O-rings which provide a fluid-tight  
15   seal around the locating end of the probe. These O-rings also  
16   function to retain the probe in the receiving port while  
17   allowing the probe to be rotated. In one embodiment of the  
18   invention, the O-rings are, instead of being located within  
19   the receiving bore of the access conduit, located about the  
20   locating end of the probe.

21           This invention also provides for a valve, for use as  
22   either an evacuation or an irrigation valve, the valve  
23   comprising a housing, an activator connected to the housing,  
24   at least a first and a second valve access conduit, both of  
25   which exit into the housing and a fluid impervious seal  
26   mounted within the housing such that activation of the  
27   activator causes the first valve conduit to move axially  
28   relative to the seal and the second valve conduit such that  
29   the seal is disengaged and the conduits are placed in direct  
30   fluid communication with each other.

31           Typically, the instrument of the invention would contain  
32   two of the above described valves. One valve would act as an  
33   evacuator control while the other valve would act as an  
34   irrigation control. Both valves communicate into a single  
35   access conduit which, when the instrument is in use,  
36   continuously flows into the patient via the receiving bore and  
37   the hollow interior of the electrostatic probe.



1            Preferably the endoscopic surgical instrument of the  
2 invention is in the form of a pistol with the "barrel" portion  
3 thereof having, at one end thereof, the receiving bore for the  
4 locating end of the endoscopic probe and, at the other end  
5 thereof, the access port for the microsurgical instruments and  
6 endoscopes.

7            The valves for controlling the evacuation and irrigation  
8 procedures may be mounted in the "handle" portion of the  
9 pistolshaped instrument. The valves may be mounted alongside  
10 one another in the handle portion and may protrude therefrom  
11 to allow finger control by the surgeon using the instrument.

12           In one alternate embodiment of the invention the surgical  
13 instrument includes a housing, a single access conduit formed  
14 in the housing, an irrigation port and an evacuation port,  
15 each port being connected through independent valves to the  
16 single access conduit. The single access conduit has a first  
17 end, and a second end which is terminated in an aperture  
18 formed in the housing. A closure is provided for the  
19 aperture. A viewing device, such as an endoscope, is  
20 insertable through the aperture and into the single access  
21 conduit. The viewing device is of sufficient length such that  
22 it is extendable slightly beyond the first end. A retractable  
23 electrode assembly is also insertable through the aperture and  
24 into the single access conduit, and is of sufficient length  
25 such that it, too, is extendable beyond the first end. The  
26 retractable electrode assembly, in one embodiment, includes  
27 two retractable RF electrodes spaced apart by a predetermined  
28 width. Each RF electrode is made from a superelastic  
29 material, e.g. typically Nickel-Titanium (NiTi) metal, is  
30 sheathed within a guiding sheath, and is slidable within the  
31 sheath such that it is extendable beyond and retractable  
32 completely within the sheath. Also, each electrode is  
33 connected to a mechanism, operable by a surgeon, for moving  
34 the electrode within the sheath. Each electrode is extendable  
35 beyond its guiding sheath by a variable length and at a  
36 predetermined angle from a longitudinal axis of the single  
37 access conduit. Further, each electrode is electrically

1 communicative with means for supplying R.F. energy and means  
2 for measuring impedance continuously on a realtime basis.

3 These and other objects and advantages of the present  
4 invention will no doubt become apparent to those skilled in  
5 the art after having read the following detailed description  
6 of the preferred embodiment which is illustrated in the  
7 several figures of the drawing.

8 IN THE DRAWINGS

9 In the following drawings:

10 FIG. 1 is a partial sectional elevation through a prior  
11 art piston valve;

12 FIG. 2 is a diagrammatic section through a semi-exploded  
13 elevation of one embodiment of the endoscopic surgical  
14 instrument of the invention;

15 FIGS. 3A-3B illustrate a tricuspid valved access port in  
16 plan (a) and elevation (b) views;

17 FIG. 4A is a section through a receiving bore of the  
18 instrument illustrating one way of locating a probe in the  
19 bore;

20 FIG. 4B is an illustration of a probe for use with the  
21 connector shown in Fig. 4A;

22 FIG. 5A is a section through a similar receiving bore  
23 showing a different way of locating a probe in the bore;

24 FIG. 5B is an illustration of a probe for use with the  
25 connector of Fig. 5A;

26 FIG. 6 is a side view illustrating in (a)-(i) various  
27 electrostatic probe operational ends;

28 FIG. 7 is a section through a valve according to the  
29 invention with the valve being in the shut position;

30 FIG. 8 is the valve of FIG. 7 in the open position;

31 FIG. 9 is a partial section through a different type of  
32 valve also suitable for use in the instrument of the  
33 invention;

34 FIGS. 10, 11, 12 and 13 are diagrammatic illustrations  
35 showing various configurations of valve operating buttons and  
36 triggers;

1        FIG. 14 is an exploded view of an alternative embodiment  
2 of the surgical instrument of the invention illustrating a  
3 disposable valve cartridge;

4        FIG. 15 is a cross section through the disposable valve  
5 cartridge illustrated in Fig. 14;

6        FIG. 16 is a partially sectioned view of another type of  
7 valve which can be used in the surgical instrument of the  
8 invention;

9        FIG. 17 is a perspective view of an alternate embodiment  
10 of the endoscopic surgical instrument having generally similar  
11 valves, as illustrated in FIG. 7-8, and a retractable  
12 electrode assembly having bipolar RF electrodes in electrical  
13 communication with a R.F. energy source and a tissue impedance  
14 monitoring device;

15       FIG. 18 is a partial sectional view taken along the line  
16 18-18 of FIG. 17;

17       FIG. 19 is a view taken along the line 19-19 of FIG. 17;

18       FIG. 20 is a side elevation view of the retractable  
19 electrode assembly shown in FIG. 17;

20       FIG. 21 is an enlarged view of the tip of the retractable  
21 electrode assembly shown in FIG. 17;

22       FIGS. 22A-22H illustrate alternate electrode  
23 configurations for the retractable electrode assembly shown  
24 in FIG. 17 and 20;

25       FIG. 23 is an enlarged view of the tip of the retractable  
26 electrode shown in FIG. 22D-22F; and

27       FIG. 24 is an alternate embodiment of the present  
28 invention including a retractable electrode assembly having  
29 a variable angle control mechanism.

30       FIG. 25(a) is an illustration of the use of multiple  
31 electrodes oriented at an angle  $\theta$ ;

32       FIG. 25(b) shows an end view of the electrodes of Fig.  
33 25(a) providing a rectangular pattern;

34       FIG. 25(c) shows a view similar to Fig. 25(b), in which  
35 two electrodes are used;

36       FIG. 25(d) illustrates the use of three electrodes for  
37 obtaining an approximate circular coagulation pattern;

1       FIG. 25(e) illustrates the use of four electrodes to  
2 achieve an approximate circular coagulation pattern;

3       FIG. 25(f) shows the use of nine electrodes to achieve  
4 an improved circular pattern;

5       FIG. 26(a) illustrates the use of superelastic metal  
6 electrodes to achieve an adjustable pattern;

7       FIG. 26(b) further clarifies the configuration of Fig.  
8 26(a);

9       FIG. 27 illustrates the use of a frusto-conical extension  
10 for deflecting the electrodes to achieve an adjustable zone  
11 of coagulation; and

12       FIG. 28 shows a connecting cable system for selectively  
13 applying bipolar or monopolar RF power to the electrodes.--  
14

#### 15       DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

16       In FIG. 2 of the accompanying drawings, the endoscopic  
17 surgical instrument of the invention is generally indicated  
18 as 20. The instrument 20 is shown to include an irrigation  
19 port 21 and an evacuation port 22. Each port, 21 and 22,  
20 is connected through independent valves 23 and 24,  
21 respectively, to a single access conduit 25. The connection  
22 between the valves 23 and 24 and conduit 25 is along connector  
23 tubes 23a and 24a.

24       The access conduit 25 leads from the valves and their  
25 respective valve conduits to a probe connector 26. This probe  
26 connector 26 is designed to receive one end, the locating end  
27 27, of a surgical probe 28 which would be used during  
28 microsurgical procedures. The connection 26 is described in  
29 more detail with reference to FIGS. 4 and 5 hereafter.

30       At or near the probe connector 26, a monopolar/bipolar  
31 radio frequency connector 29 is located. As illustrated,  
32 this is in the form of a R.F. connector. The advantage of a  
33 R.F. connector is that it is an industry standard and can be  
34 used for connecting the instrument 20 to standard R.F. energy  
35 sources marketed by a number of different manufacturers.

36       The radio frequency connector 29 exits into the access  
37 conduit 25 where it makes connection with a point 30, on the

1 locating end 27 of a probe 28 received by the probe connector  
2 26.

3 The surgical instrument 20 also includes a port 31 which  
4 allows the surgeon to insert microsurgical instrumentation and  
5 viewing devices along the access conduit 25 and the bore of  
6 the hollow probe 28 to exit from the end 32 thereof. The port  
7 31 should provide a fluid-tight seal when no microsurgical  
8 instrumentation is being used with the surgical instrument 20.  
9 This will prevent fluid, which may be moving along the access  
10 conduit 25 to or from the patient, from leaking.

11 Typically, the access port 31 is in the form of a  
12 commercially available tricuspid valve as illustrated in FIGS.  
13 3(a) and (b). In these figures, the valve 31 is shown as  
14 being constituted by three segments 32 which in plan view are  
15 wedge-shaped and which together form the disc shaped sealing  
16 portion of the valve. The segments 32 are held together by  
17 means of a circumferential ring 33 which biases the three  
18 segments 32 together to form a fluid-tight seal. In use, the  
19 microsurgical instrumentation are inserted through the valve  
20 at a point 34 where the apexes of the segments 32 come  
21 together. This insertion forces the elements of the valve  
22 apart to allow ingress of the microsurgical instrumentation.  
23 The effect thereof is shown in broken lines in FIG. 3(b).  
24 When the instrumentation is removed from the valve 31, the  
25 segments 32 are pulled together to form the seal.

26 In FIG. 4 the probe connector 26 is shown to be  
27 constituted by a receiving bore which is coaxial with the  
28 fluid access conduit 25. In practice, the diameter of this  
29 bore would be the same as that of the access conduit 25 and  
30 would be sized to receive the locating end 27 of the probe 28  
31 in a relatively close fit. Within the bore forming the probe  
32 connector, a plurality, typically two, O-rings 36 are located.  
33 When the locating end 27 is inserted into the bore 26 these  
34 O-rings provide a snug, fluid-tight seal about the end 27.  
35 Once the locating end 27 of the probe is received within the  
36 bore 26 it is capable of being rotated about its longitudinal  
37 axis, by means of a knurled rotation knob 37 located between

1 the locating end 27 and the operational end 32 of the probe  
2 28.

3 The probe 28 would typically be made of a electrostatic  
4 conductive material coated with a non-conductive material such  
5 as heat shrink polyolefin or Teflon. Electrostatic/radio  
6 frequency energy is passed along the probe 28 from the radio  
7 frequency connector 29 via electrostatically conductive plates  
8 38 located within the bore of the probe connector 26 and onto  
9 the end 30 of the probe 28. The end 30 is so designed such  
10 that when the locating end 27 of the probe is received by the  
11 probe connector 26, electrostatic connection is made between  
12 the plate 38 and the connector 30. This allows the surgeon  
13 to pass energy into the patient being operated on.

14 An alternative radio frequency connector is illustrated  
15 in FIG. 5. In this case, the R.F. connector 29 exits into the  
16 bore 26 in the form of a pin 39. In the conductive end 30 of  
17 the probe 28 an L-shaped slot 40 is formed. As the probe 28  
18 is inserted into the receiving bore 26, the pin 39 engages the  
19 axially-orientated leg 41 of the L-shaped slot 40. When the  
20 probe can be inserted no further along the bore it is twisted,  
21 in this case in an anti-clockwise direction, such that the pin  
22 39 and the axially transverse leg 42 of the L-shaped slot 40  
23 engage each other to lock the probe 28 into position. In this  
24 embodiment the probe 28 cannot be rotated by means of the  
25 knurled knob 37.

26 FIG. 5 further illustrates an alternative positioning of  
27 the O-rings 36. In this case they are located on the locating  
28 end 27 of the probe 28.

29 From FIGS. 4 and 5, although not shown, it will be  
30 apparent that the diameter of the operational shank 28a of the  
31 probe 28 can be variable. Typically, the probe, as shown,  
32 would have a diameter of 5mm. This diameter can, however, be  
33 increased to 10mm which would be close to the diameter of the  
34 locating end 27 of the probe, as well as that of the internal  
35 bore diameter of the access conduit 25. The advantage of 10mm  
36 diameter probes is that the evacuation of removed tissue and  
37 objects such as the gall-stones can be more effectively  
38 achieved. Obviously, when the bore of the operating shank 28a

1 of the probe, the locating end 27 and the access conduit 25  
2 are all 10mm in diameter, the diameter of the evacuation port  
3 22 and its related valve 24 and connector tube 24a must also  
4 be 10mm.

5 In FIG. 6(a) to (i), a side view of number of different  
6 electrode shapes are illustrated. It will be appreciated that  
7 the electrode tips could be either monopolar or bipolar. In  
8 the case of bipolar electrodes, only one electrode is  
9 illustrated since a second electrode is fully obscured by the  
10 visible electrode. These electrode tips would be located on  
11 the operating end of the probe 28.

12 As can be seen from the figure, a number of the tips are  
13 not symmetrical about the longitudinal axis of the probe 28.  
14 It is for this reason that it is desirable for the probe 28  
15 to be mounted on the instrument in such a manner to allow for  
16 a rotation of the probe about its longitudinal axis. As has  
17 been previously indicated, this will give the surgeon the  
18 opportunity of rotating any non-symmetrical tips, inside the  
19 patient, without having to rotate his or her wrist.

20 This invention extends also to an electrostatic probe 28,  
21 substantially as described in any of the FIGS. 4 to 6.

22 The details of one type of irrigation/evacuation valve  
23 are illustrated in FIGS. 7 and 8. The valve 24 indicated in  
24 both figures comprises a housing constituted by a hollow tube  
25 50 and an activator in the form of a button 51 formed  
26 integrally with the tube 50. A fluid impervious seal 52 is  
27 located within the tube 50. Referring specifically to FIG.  
28 7, in which the valve is shown in the shut position, it can  
29 be seen that the seal 52 lies between a first valve conduit  
30 53 which leads to the evacuation port 22 (not shown) and a  
31 second valve conduit in the form of connector tube 24a which  
32 leads into the primary access conduit 25 of the surgical  
33 instrument. In effect, the seal 52 prevents the conduits 53  
34 and 24a from being in communication with each other.

35 The first valve conduit 53 is mounted onto the wall of  
36 the tube 50 and opens into the interior of the tube 50 through  
37 a hole 54. Between the seal 52 and the button portion 51 of  
38 a tube 50, a spring 55 is located. On the side of the seal

1 52, opposite to which the spring is located, a tubular insert  
2 56 is located. This tubular insert has a snug but slidable  
3 fit over the outer wall of the second valve conduit 24a as  
4 well as a tight, fluid impervious fit into the inner bore of  
5 the tube 50. This tube 56 acts as a stop which prevents the  
6 spring 55 from pushing the seal 52 out of the hollow tube 50.

7 To open the valve, as is illustrated in FIG. 8, an  
8 activating force, applied along a line F to the button 51,  
9 will cause the button to move from the position indicated in  
10 broken lines to the illustrated open-valve position. As the  
11 button moves, so does the hollow tube 50, taking the first  
12 valve conduit 53 along with it. In addition, the leading edge  
13 57 of the second valve conduit 24a bears against the seal 52  
14 causing the seal to move relatively to the tube 50. This in  
15 turn disengages the seal from sealing the hole 54 in the wall  
16 of the tube 50. The movement of the first valve conduit 53,  
17 relative to the second valve conduit 24a, places the  
18 respective openings 54 and 58 of these two conduits in fluid  
19 communication with each other thereby allowing an unobstructed  
20 fluid flow along both access conduits.

21 Upon release of the force on the button 51, the bias of  
22 the spring 55 will return the valve to its shut position.

23 It is evident from the construction of the valves  
24 illustrated in FIGS. 7 and 8 that they can be readily cleaned  
25 by commonly used cleaning such as flushing. In addition, the  
26 valves have almost no areas where blood and tissue  
27 accumulation and coagulation can occur, and if such  
28 accumulation and coagulation does occur the valves cannot be  
29 jammed in the open position. This is because the spring  
30 biasing the valve into its closed position is located in an  
31 effectively sealed area. Furthermore these valves have been  
32 tested to a pressure of up to 100 psi without the integrity  
33 of the valve seal being adversely affected.

34 An alternative form of valve, to that illustrated in  
35 FIGS. 7 and 8 above, is shown in FIG. 9. In the figure the  
36 valve is shown to include a generally cylindrical valve body  
37 60, an activating button 61 and a plunger 62. A hollow bore  
38 runs down the center of the valve body 60 and contains the



1 valve seal 63. The valve seal 63 is made up of a circular  
2 washer 63a and a sealing O-ring 63b and is screwed onto the  
3 bottom of plunger 62. The valve seal 63 is biased into its  
4 illustrated sealing position by means of a spring 64 located  
5 in the bottom part of the valve body 60.

6 To open the valve, the button 61 is depressed so that the  
7 plunger 62 forces the valve seal 63 downwards against the bias  
8 of the spring 64 to a position shown in broken lines 63', in  
9 the figure. As a result, a fluid path, indicated by arrows  
10 65, is opened between an upper pair of cutouts 66 and a lower  
11 pair of cutouts 67. Each pair of cutouts opens into the  
12 hollow bore in the center of the valve body 60 and, when this  
13 valve is inserted into the surgical instrument, into either  
14 an evacuation or irrigation conduit. Closure of the valve is  
15 achieved by releasing the button and allowing the spring 64  
16 to return the valve seal 63 to the sealing position.

17 One advantage of this embodiment of the valve is that it  
18 is easily removed from and inserted into the surgical  
19 instrument of the invention. Accordingly the valve can easily  
20 be removed for cleaning or disposal and replacement. This is  
21 further illustrated below with respect to FIG. 13. It is  
22 sufficient here to mention only that the surgical instrument  
23 is provided with a receiving bore for each valve and that the  
24 valve includes a plurality (in this case 3) O-rings 68 which,  
25 when the valve is inserted into its respective receiving bore,  
26 provide a number of fluid tight seals against the inside of  
27 the bore.

28 Either of the two types of valve described in FIGS. 7 to  
29 9 can be used on the instrument 10. Typically one valve would  
30 act as an evacuation valve while the other as an irrigation  
31 valve. Different types of arrangements of valves and valve  
32 activation means are illustrated in the following 4 figures.

33 One way of activating the valve is by means of a rocker-  
34 shaped trigger 70 illustrated in FIG. 10. The trigger 70 is  
35 pivotally mounted on a point 72 on the handle 74 of the  
36 pistol. Depressing the trigger 70 to operate the irrigation  
37 valve 71 would not interfere with the operation of the  
38 evacuation valve 73. Similarly, operation of the trigger 70

1 to operate the evacuation valve 73 would in no way effect the  
2 operation of the irrigation valve.

3 In FIG. 11 a trigger mechanism 76 is shown for operation  
4 of only one of the buttons. The other button 78 would be  
5 located for operation by means of the surgeon's thumb in a  
6 position removed from the trigger 76. This could, for  
7 example, be near the top end of the handle portion of the  
8 instrument.

9 Yet a further positioning of the buttons 71 and 73 is  
10 indicated in FIG. 12. In this instance, the buttons protrude  
11 from the top rear of the pistol handle and are located side-  
12 byside. To prevent confusion between evacuation and  
13 irrigation procedures, the tops of the buttons have different  
14 shapes. So, for example, the button to manipulate the  
15 evacuation valve could be concave while the button for  
16 manipulating the irrigation valve could be convexly shaped.

17 FIG. 13 illustrates still another arrangement of buttons  
18 and valves, in this case an arrangement particularly suited  
19 to the valve shown in FIG. 9.

20 In this figure only the pistol grip 90 of the surgical  
21 instrument of the invention is shown. An irrigation port 92  
22 and evacuation port 94 enter the pistol grip 90 at the bottom  
23 of its handle portion. The ports 92, 94 are, in use,  
24 respectively connected to irrigation and evacuation conduits  
25 (not shown) and, to this end, suitable connectors, as  
26 illustrated, are provided.

27 The irrigation port 93 communicates with the main access  
28 conduit 96 (referenced as 25 in FIGS. 2, 4 and 5) along an  
29 irrigation conduit 98 which extends from the irrigation port  
30 93 and into the rear of the bore 100 which houses an  
31 irrigation valve 102. From there it extends along the bore  
32 100 to a point near the front of the bore from where it exits  
33 into the body of the grip 900 to enter rear of the bore 104  
34 which houses an evacuation valve 106. the irrigation conduit  
35 extends directly across the bore 104 at this point and becomes  
36 a central conduit 108 which communicates with the access  
37 conduit.

1       On the other hand, the evacuation port 94 communicates  
2       with an evacuation conduit 105 which extends along the pistol  
3       grip 90 directly into the front of the bore 104, down to the  
4       bore 104 to its rear from where it exits into the central  
5       conduit 108.

6       In the position shown, both the irrigation and evacuation  
7       valves 102, 106 respectively, are shown in the off or shut  
8       configurations and neither evacuation or irrigation can take  
9       place. Should irrigation of the patient be required, the  
10      dish-shaped irrigation button 110 is depressed and the valve  
11      102 opens (ie. its valve seat moves to the right in the  
12      drawing) to allow irrigation fluid to pass along the  
13      irrigation conduit 98 and into the bore 104. In this bore 104  
14      the evacuation valve 106 is in the off configuration.  
15      However, a fluid path exists across the pair of cutouts (67  
16      in FIG. 9) and therefore the irrigation fluid can pass through  
17      the body of the valve 106 and into the central conduit 108  
18      and, from there, into the access conduit 96.

19      When evacuation is desired the irrigation button 110 is  
20      released and the spring associated with the irrigation valve  
21      102 biases it into the shut or off configuration. Thereafter  
22      the flat topped evacuation button 112 is depressed to open the  
23      evacuation valve 106. This allows the patient to be evacuated  
24      along the main access conduit 96, into the central conduit  
25      108, then from the rear to the front of the bore 104 and, from  
26      there, out along the evacuation conduit 105.

27      As has been indicated earlier, the valves 102, 106 are  
28      easily inserted into and removed from their respective bores  
29      100, 104. This allows the pistol grip 90 (which is typically  
30      stainless steel and is reusable) to be cleaned efficiently.  
31      The valves, typically being of plastic and being difficult to  
32      clean, can be discarded and replaced with new valves.

33      A variation on this theme of discardable valves is  
34      illustrated in FIG. 14. In this figure the surgical  
35      instrument is shown to include a pistol grip 120, a surgical  
36      probe 122, which can be screwed into the front of the pistol  
37      grip 120 and a radio frequency connector 124 which screws into  
38      the back of the grip 120.

1       The instrument also includes a removable (and disposable)  
2 valve cartridge 126. The cartridge 126 includes an irrigation  
3 pipe 128 and an evacuation pipe 130 both of which are  
4 individually operated by valves (as will be further  
5 illustrated in FIG. 15) under action of button-shaped  
6 actuators 132. Both the irrigation and evacuation pipes  
7 communicate into a single conduit (not shown) which runs down  
8 the center of a male connector fitting 134. Where the  
9 cartridge 126 is inserted into the grip 120 the connector 134  
10 fits into the base of a central conduit 136 which, in turn,  
11 opens up into the main access conduit 138 of the instrument.  
12 When the cartridge 126 is located in the grip 120 the  
13 actuators 132 are located directly below a pair of operating  
14 triggers 140 which can be used to operate the  
15 irrigation/evacuation procedures described before.

16       Finally, when the cartridge 126 is in place, it is held  
17 there by means of a retainer clip 142 which clips in behind  
18 the cartridge 126. The retainer clip 142 has apertures 144  
19 formed in it to allow the irrigation and evacuation pipes 128,  
20 130 to pass through it.

21       Although it will be apparent that the valve types  
22 described above are also suitable for use in the cartridge  
23 126, a further valve configuration is illustrated in FIG. 15,  
24 which illustrates the cartridge 126 in greater detail.

25       In this figure, the cartridge 126 is shown to include an  
26 irrigation conduit 150 and an evacuation conduit 152, both of  
27 which lead to a central access conduit 154 which extends down  
28 the center of the male connector 134. Irrigation and  
29 evacuation procedures are controlled by irrigation and  
30 evacuation valves 156 and 158, respectively.

31       The irrigation valve 156 consists of a valve seal 160  
32 mounted onto a stem which is screwed into an activator button  
33 132a. A fluid tight seal is provided for the valve 156 by an  
34 O-ring 168 mounted onto the cap 132a. The valve seal 160  
35 seals against a valve seat, formed at the junction between the  
36 irrigation conduit 150 and the central access conduit 154 and  
37 is held in the sealing position (as shown) by a spring 162.

1        Access to the valve seat is through a hole 164 formed  
2        into the top (as shown in the drawing) of the cartridge 126.  
3        This hole 164 can be closed off with a cap 166 and allows the  
4        irrigation valve 156 to be inserted into the cartridge 126.  
5        This is done by inserting the valve seal 160 and its  
6        associated stem into the hole 164 from above and inserting the  
7        spring 162 from below. Thereafter the cap 132a can be screwed  
8        onto the stem to hold the entire valve 156 in place.

9        To operate an irrigation procedure the button 132a is  
10       depressed to move the valve seal 160 clear of its seal to open  
11       a fluid path between the irrigation conduit and the central  
12       access conduit. Releasing the button 132a causes the spring  
13       162 to force the seal 160 back into its seat thereby  
14       automatically shutting the valve.

15       The evacuation valve 158 is of a different construction.  
16       In this valve 158, the valve seal 170, in its off position as  
17       shown, seals the mouth of the evacuation conduit 152.

18       In operation, the seal 170 is moved under action of a  
19       plunger and evacuation button 132b from the position shown to  
20       a position 170' in which an end of a conduit 174, formed  
21       through the seal 170, aligns with the central access conduit  
22       154. At the same time the other end of the conduit 174 is  
23       aligned with the evacuation conduit 152 and evacuation can be  
24       accomplished. By releasing the button 132b, the spring 172  
25       biases the seal 170 back into its sealing position.

26       Assembly of this evacuation valve 158 is by inserting the  
27       entire valve mechanism into its valve bore and sealing a  
28       collar 176 in the bore.

29       As has been indicated with reference to FIG. 14, the  
30       cartridge 126 is of the disposable type and is intended for  
31       use only once. Accordingly the considerations of valve  
32       flushing (during cleaning) are not entirely applicable here.

33       In FIG. 16 yet another type of valve, which can be used  
34       as either an irrigation or an evacuation valve, is  
35       illustrated.

36       The valve, generally indicated as 180, is shown to  
37       include a hollow cylindrical valve body 182 which is sealed  
38       at its lower end by a valve seal 184 and at the other by an

1 activator button 186. The activator button 186 seals against  
2 the valve body with an O-ring 188 and is connected to the  
3 valve seal 184 by means of a plunger 190.

4 To open the valve 180, the button 186 is depressed  
5 against the bias of a spring 192 to move the valve seal 184  
6 to the position indicated in broken lines. This opens a fluid  
7 path 194 between an opening 196 formed in the sidewall of the  
8 valve body and its lower end. Releasing the button 186 allows  
9 the spring 192 to force the seal 184 back into the closed  
10 position.

11 One advantage of this valve is that it is very simple and  
12 inexpensive to manufacture and can, therefore, readily be  
13 disposed of.

14 Finally, it will be apparent to anyone skilled in the  
15 art, that the surgical instrument of this invention could be  
16 made from any suitable material. In the event that the  
17 instrument is intended for single use, plastic material could  
18 be used. Alternatively, for reusable or reposable instrument,  
19 the instrument can be made of a more durable material.

20 FIG. 17 is a perspective view of an endoscopic surgical  
21 instrument 200 which is an alternate embodiment of the  
22 surgical instrument 20 described above. FIG. 18 is a partial  
23 sectional view of a portion of the instrument 200 taken along  
24 the line 18-18 of FIG. 17 and FIG. 19 is another view of the  
25 instrument 200 taken as indicated by the line 19-19 of FIG.  
26 17. FIG. 20 illustrates the retractable electrode assembly  
27 202. When viewed together, FIG. 17-20, illustrate the  
28 instrument 200 including an endoscopic instrument 201, a  
29 retractable RF electrode assembly 202, an continuous  
30 irrigation and evacuation assembly 203, a R.F. energy source  
31 285, and a tissue impedance monitoring device 284. It will  
32 be appreciated that, although two retractable RF electrodes  
33 are illustrated and subsequently described, in alternate  
34 embodiments the retractable electrode assembly could have one  
35 or more than two retractable RF electrodes. Also, although  
36 a bipolar retractable RF electrode assembly is illustrated and  
37 subsequently described, it will be appreciated that a  
38 monopolar retractable RF electrode assembly could be used.

1       The assembly 203 includes a housing 210, an irrigation  
2       valve assembly 214, and an evacuation valve assembly 220. The  
3       housing 210 includes an elongated portion 228 having a  
4       generally oval cross section. The portion 228 includes a free  
5       tip end 230 and a secured end which is attached to a handle  
6       portion 232. The portion 232 is held by the surgeon, and the  
7       portion 228 is surgically introduced into a body cavity (not  
8       shown) of the patient. A single access conduit 212 (a portion  
9       of which is best seen in FIG. 18 and 19) is formed between an  
10      inner surface of the portion 228 and the objects carried  
11      within the portion 228. The conduit 212 is disposed along the  
12      entire longitudinal length of the portion 228 and is  
13      functionally similar to the conduit 25 (FIG. 2) in that it  
14      permits the irrigation and evacuation of fluids into and out  
15      from the body cavity into which the portion 228 is inserted.  
16      The conduit 212 is open at the tip end 230 and can be  
17      accessed, at its opposite end, via an aperture and associated  
18      closure 226 formed in the handle portion 232. The closure 226  
19      is in the form of a tricuspid valve and is substantially  
20      similar to the valve 31 illustrated and described above (FIG.  
21      2).

22      The irrigation valve and the evacuation valve assemblies  
23      214, 220 are substantially similar to the irrigation and  
24      evacuation valves 23, 24 described above (FIG. 2). The valve  
25      assemblies 214, 220 operate in a similar manner to valves 23,  
26      24 (FIG. 7, 8). Depressing the valve assemblies 214 or 220  
27      permits the communication of fluid in a valve first conduit  
28      216 (or 222) with a valve second conduit 218 (or 224). Each  
29      of the valve second conduits 218 and 224 are in fluid  
30      communication with the conduit 212 (in the same manner that  
31      the conduits 23a, 24a are in fluid communication with the  
32      conduit 25, FIG. 2). Thus, when the valve assembly 214 is  
33      operated, irrigation fluid can be communicated to the conduit  
34      212 and out through the tip end 230, and delivered to the body  
35      cavity. In a similar manner, fluids in the body cavity can  
36      be evacuated if the valve assembly 220 is operated.

37      The retractable electrode assembly 202 includes a means  
38      for guiding the angular orientation of the electrode or guide

1 sheath 248, an endoscope sheath 238, a electrode movement  
2 mechanism 236, a tissue impedance measurement device 284, and  
3 a R.F. energy source 285. The sheath 248 is generally  
4 parallel to the scope sheath 238. The sheath 248 and the  
5 sheath 238 are each insertable into an opening of an insert  
6 flange 242, into the aperture of the handle portion 232 of the  
7 assembly 203. The sheath 248 and the sheath 238 are  
8 insertable within the conduit 212 and are each of sufficient  
9 length such that when each is fully inserted within the  
10 conduit 212, each extends slightly beyond the tip end 230 of  
11 the cylindrical portion 228.

12 The endoscopic instrument or endoscope 201 is  
13 substantially similar to the endoscope instrument described  
14 above, and can be any of a number of devices known in the  
15 prior art. An eyepiece 204 is shown attached to the endoscope  
16 201. The endoscope 201 is slid into the scope sheath 238  
17 until the eyepiece 204 engages a flange 240 which is attached  
18 to the sheath 238. Thus, the endoscope 201, and the sheath  
19 248 of the retractable electrode assembly 202 are both  
20 insertable within the portion 228 of the irrigation and  
21 evacuation assembly 203.

22 Each of two RF electrodes 250a, 250b is sheathed within  
23 its respective guide sheath 248a, 248b. Although the  
24 illustrated embodiment depicts two RF electrodes, it will be  
25 appreciated that the assembly 202 could have one or more than  
26 two electrodes. Each electrode 250a, 250b includes a first  
27 or distal end 249a, 249b, a second, or proximal end 247a,  
28 247b, and a central portion (not shown) disposedly connected  
29 therebetween. A coating of insulation 246 is disposed onto  
30 the bare electrode 250. The insulation coating 246 may be in  
31 the form of a tube of material (such as teflon) heat shrunk  
32 around the bare electrode 250. Alternately, the insulating  
33 coat 246 may be powder deposited, using vacuum deposition  
34 techniques, onto the bare electrode 250. In either case,  
35 nearly the entire length of the bare electrode 250 is covered  
36 by the insulating coat 246.

37 The electrodes 250a, 250b have a generally constant  
38 diameter throughout its entire length and are sized such that



1 they can be slid within the sheaths 248a, 248b. That is,  
2 there exists a sufficient clearance (e.g. 0.005 inch) between  
3 the outside diameter of each of the insulating coats 246a,  
4 246b of the electrodes 250a, 250b and the inner diameter of  
5 the respective sheaths 248a, 248b. Each electrode 250a, 250b  
6 is made from a superelastic metal material, e.g. typically a  
7 Nickel-Titanium (NiTi) metal alloy. The guide sheaths 248a,  
8 248b are made from a rigid plastic or coated metal tubing  
9 which forms a rigid conduit that guides, i.e. deforms, the  
10 electrode along a predetermined path.

11 As best seen in FIG. 19, the electrodes 250a, 250b and  
12 their respective sheaths 248a, 248b are contained within the  
13 cross sectional envelope of the portion 228. Thus, the  
14 required incision into the patient need only accommodate the  
15 cross sectional area of the portion 228. The presence of the  
16 extendable electrodes does not increase the size of the  
17 required incision. It should be also noted that each  
18 electrode 250a, 250b descends downwardly into the field of  
19 view of the endoscope 201. In this manner the surgeon is able  
20 to view the extension of each electrode 250a, 250b beyond the  
21 end of the sheath 248a, 248b.

22 The two electrodes 250a, 250b and their respective  
23 insulators 246a, 246b are encased within their respective  
24 guide sheaths 248a, 248b which are encased within a plastic  
25 insulating covering 244. The electrodes 250a and 250b encased  
26 within the plastic covering 244 exits the housing 232 through  
27 the opening in the flange 242.

28 Each electrode 250a, 250b is in parallel electrical  
29 communication with a tissue impedance measuring device 284 and  
30 a R.F. energy source 285. The covering 244 enters the  
31 movement mechanism 236 through an opening 260 formed in a  
32 sleeve 256 of the mechanism 236. The electrodes 250a, 250b  
33 and their respective insulators 246a, 246b exit from the  
34 covering 244 and each of the second ends 247a, 247b, of each  
35 of the electrodes 250a, 250b are attached to connecting pins  
36 272a, 272b, respectively. The connecting pins 272a, 272b are  
37 mounted at an end of a plunger 264. Each connecting pin 272a,  
38 272b is in communication with a wire 274a, 274b each of which

1 passes through the plunger 264, through an opening 278, and  
2 into an insulated line 276 which is terminated in a plug 280  
3 which is matingly engagable with a receptacle 282 of the  
4 tissue impedance measuring device 284. The R.F. source 285  
5 is in electrical communication with the impedance measuring  
6 device via electrical lines 283a and 283b. The source 285 and  
7 the impedance measuring device 284 are connectable in parallel  
8 in order to get realtime impedance measurement of tissue  
9 engaged between the first ends 249a, 249b of each of the  
10 electrode 250a, 250b.

11 The movement mechanism 236 includes a finger ring portion  
12 252, and a thumb ring portion 254. The finger ring portion  
13 252 is a generally flat plate having finger loops 251a, 251b  
14 formed therein. A passage 262 is formed through the finger  
15 ring portion 252 such that the longitudinal axis of the  
16 passage 262 is disposed between each finger loop and lies  
17 coplanar with the plane of each finger loop. The sleeve 256,  
18 and a cylinder 258 are partially inserted into opposite ends  
19 of the passage 262. The sleeve 256 has a passage  
20 longitudinally formed therein so as to receive the covering  
21 244. The cylinder 258 has a passage longitudinally formed  
22 therein which is aligned with the passage of the sleeve. The  
23 plunger 264 is slidable within the passage of the cylinder  
24 258. One end of the plunger is attached to the thumb ring  
25 portion 254, and the connection pins 272a, 272b are mounted  
26 to the other end of the plunger 264. The outer surface of the  
27 plunger 264 is visible through an access cutout 270 formed in  
28 the cylinder 258. In one embodiment, an indicator post 266  
29 is attached to the outer surface of the plunger 264 and passes  
30 through the access cutout 270 to give an immediate visual  
31 indication of the position of the plunger 264 within the  
32 cylinder 258. In a preferred embodiment, the outer surface  
33 of the plunger 264 is scored with a plurality of indicator  
34 marks 268 to provide a visual indication of the position of  
35 the plunger 264 within the cylinder 258, which corresponds to  
36 variable length of extension of each of the electrodes beyond  
37 their respective insulating sheaths.

1 In operation, the irrigation and evacuation valves, and  
2 the endoscope operate as described above. Regarding the  
3 retractable electrode assembly 202, a free hand of the surgeon  
4 is used to operate the movement mechanism 236. The surgeon's  
5 fingers are engaged within the finger ring loops and the thumb  
6 is engaged within the thumb ring portion. The thumb either  
7 pushes or pulls on the thumb ring thereby moving the attached  
8 plunger 264 into or out of the cylinder 258 and the passage  
9 262. As the plunger 264 moves each of the first ends 249a,  
10 249b of each of the electrodes 250a, 250b move because the  
11 connection pins 272a, 272b mounted to the plunger are attached  
12 to each of the second ends 247a, 247b of each of the  
13 electrodes 250a, 250b. Thus, as the plunger moves in the  
14 direction of the arrow A, the central portions of each of the  
15 electrodes moves within their respective insulators in the  
16 direction of the arrow B, and the first ends 249a, 249b move  
17 in the direction of the arrow C.

18 FIG. 21 illustrates the first end 249 of the electrode  
19 250. The guide sheath 248 is formed with a bend at one end.  
20 The electrode 250 slides within the sheath 248 and exits the  
21 sheath 248 under the guidance of the sheath 248. The  
22 insulating cover 246 permits the easy sliding of the electrode  
23 within the sheath 248. Although a bend of 90 degrees is  
24 illustrated, it will be appreciated that a bend of any angle  
25 may be formed in the sheath 248 so as to guide the electrode  
26 250 into a variety of angular dispositions. It should be  
27 noted that the electrode 250 is bare in the vicinity of the  
28 first end 249. A predetermined length value L, measured from  
29 the tip of the electrode to the end 255 of the insulating coat  
30 246, represents the length of the electrode 250 that is bare  
31 or uncoated. Typical values for L range from 0 to 3 cm.

32 The first ends of each electrode extends beyond its  
33 respective sheath 248 by a length greater than the  
34 predetermined extension length L in order to permit the bare  
35 electrode to penetrate a tissue portion up to the full L  
36 value. Further, the first ends of each needle electrode are  
37 separated by a predetermined separation width W (typically  
38 0.1-2.0 cm) and each first end forms a predetermined angle  $\theta$

1 with respect to the longitudinal axis of portion 228. In the  
2 illustrated embodiment, the angle  $\theta$  is 90 degrees. Typical  
3 values for  $\theta$  range between 0 and 360 degrees.

4 During surgical procedures, the tip end 230 of the  
5 portion 228 of the instrument 200 is brought adjacent to a  
6 target tissue area of the body cavity. The first ends of each  
7 electrode are extended beyond their respective sheaths such  
8 that each first end is embedded into the soft target tissue  
9 area thereby defining a tissue portion engaged between the  
10 adjacent first ends of each electrode. The power source is  
11 energized and R.F. energy is transmitted from one electrode  
12 to the adjacent electrode. The energy transmission causes a  
13 coagulation of the tissue portion engaged between the adjacent  
14 electrodes and ablation of the target tissue.

15 Using the present invention, the surgeon can predict and  
16 control the amount of tissue ablation/coagulation with greater  
17 accuracy and safety. As described above, the spacing between  
18 the two parallel first ends of each electrode remains constant  
19 at some predetermined W value, e.g. 1.0 cm. Also, the  
20 extension of the electrodes beyond the insulators at a given  
21 angle, i.e. the depth of penetration of each first ends of  
22 each electrode into the soft tissue portion, can be precisely  
23 controlled by observing the indicator marks on the plunger.

24 Predictable and precise tissue ablation is therefore possible  
25 with the present invention because the depth of each first end  
26 of each electrode in soft tissue can be precisely controlled  
27 by the surgeon. That is, the surgeon can predict a  
28 cylindrical zone of ablation by controlling the depth of the  
29 retractable first ends into the soft tissue portion. This  
30 precise depth control enables the surgeon to predict the zone  
31 of ablation with greater accuracy and safety than prior art  
32 non-retractable monopolar RF devices, or prior art laser  
33 delivery systems.

34 The cellular structure of body tissue contains water  
35 which is a conductor of electrical energy. Consequently, a  
36 portion of body tissue also has an associated resistance or  
37 impedance value. In prior art monopolar electrode devices,  
38 tissue impedance is difficult to measure. However, in the

1 present invention, precise impedance measurement of the soft  
2 tissue in the proximity of the bipolar electrodes is possible.  
3 In the present invention, during the tissue coagulation  
4 process simultaneous measurement of the impedance of the  
5 tissue engaged between the extended first ends of the  
6 electrodes signals the completion of the tissue coagulation  
7 process and provides assurance and confirmation to the  
8 surgeon.

9 R.F. energy applied to the tissue engaged between the  
10 first ends of the two electrodes causes the tissue to  
11 coagulate which decreases the water content associated with  
12 the tissue. As the water content decreases the conductivity  
13 of the tissue decreases. For a constant R.F. energy, as the  
14 conductivity decreases the impedance (or resistance)  
15 associated with the tissue increases. The tissue impedance  
16 is highest when the tissue is completely coagulated, since  
17 coagulated tissue has a minimum amount of water content and  
18 current flow is blocked from one electrode to the other  
19 electrode. However, at the beginning of the ablation  
20 procedure, the tissue impedance is at a minimum because the  
21 water content of the tissue is at its highest level and the  
22 tissue is a good conductor and allows the maximum current to  
23 flow from one electrode to the other. During the ablation  
24 procedure, as the tissue coagulates the water content  
25 decreases and the tissue impedance increases. The tissue  
26 impedance measurement device 284 can be designed to transmit  
27 an variable frequency audible signal, i.e. a beeping tone,  
28 when the tissue impedance is at its lowest value. As more  
29 tissue is ablated and as the tissue impedance reaches its  
30 highest value the audible signal decreases in frequency. In  
31 the present invention, the tissue impedance is monitored or  
32 measured on a relative basis. That is, the impedance measured  
33 or monitored is the impedance of the tissue engaged between  
34 the two needle electrodes.

35 FIG. 22A through 22H illustrate alternate electrode  
36 configurations. It will be noted that the preferred  
37 embodiment of the present invention includes two electrodes  
38 with a  $\theta$  of 90 degrees, and a L value of 0-3 cm, and a W

1 value of 0.1-2.0 cm. It will be appreciated that a variety  
2 of electrode configurations, with associated L, W, and  $\theta$   
3 values within the above specified ranges, are possible.  
4 However, it is generally preferable to limit the total number  
5 of electrodes to six or less.

6 It will be noted that in the embodiments illustrated in  
7 FIG. 22A-22C, 22G-22H, the electrodes 250 are guided by the  
8 shape of the sheath 248. That is, the electrodes can be  
9 directed towards or away from each other if the guide sheaths  
10 are angled towards or away from each other. Similarly,  
11 different  $\theta$  values are possible if the sheaths are formed with  
12 the appropriately angled bends.

13 However, in the embodiments illustrated in FIG. 22D-22F,  
14 the sheaths are substantially straight and the electrodes  
15 themselves are bent in order to direct them in certain  
16 orientations. This feature is more clearly shown in FIG. 23  
17 which illustrates a typical electrode having a bend formed at  
18 the location depicted by numeral 257. When the electrode is  
19 disposed within the sheath 248, the electrode 250 is in  
20 contact with at least one portion 259 of the inner surface of  
21 the sheath 248 because of the bend 257. When the electrode  
22 is extended beyond the sheath (shown in phantom lines), the  
23 electrode "flattens" within the sheath 248 while the electrode  
24 tip angles away from the sheath centerline in accordance with  
25 the bend 257 formed in the electrode.

26 FIG. 24 illustrates a retractable electrode surgical  
27 instrument 300 which is an alternate embodiment of the  
28 retractable electrode instrument 200 (FIG. 17). The  
29 instrument 300 includes many of the same elements as the  
30 instrument 200. These identical elements are identified with  
31 the same reference numeral as shown in FIG. 17. In this  
32 embodiment, each electrode 250a, 250b is enclosed within a  
33 bendable guiding sheath 290a, 290b. A guide wire 293a, 293b  
34 is disposed within each sheath 290a, 290b and includes a first  
35 end 289a, 289b and a second end 291a, 291b. Each first end  
36 289 of each guide wire 293 is attached (e.g. welded or  
37 adhesively bonded) to an inner surface of a bendable or  
38 bellows portion 292 of the sheath 290 at a location proximate

1 the open end of the sheath 290. Each second end 291 is  
2 attached to a lever or knob 294 which is mounted to an outer  
3 surface of a housing 291. The housing 291 is similar to the  
4 housing 232 and includes communication ports for an irrigation  
5 valve and an evacuation valve (neither shown). In operation,  
6 when there is no tension on the guide wires the sheaths are  
7 straight within the conduit, i.e.  $\theta$  is 0 degrees. As the  
8 surgeon pulls back on the knob or lever, the wires are  
9 tensioned and the tips of each sheath is pulled back as  
10 illustrated until a desired  $\theta$  value is obtained. In this  
11 embodiment, both the L and the  $\theta$  values can be adjusted by the  
12 surgeon in situ.

13 With reference to Fig. 25, alternative embodiments for  
14 the electrodes of the present invention are shown. Fig. 25(a)  
15 illustrates an electrode configuration similar to that shown  
16 in Fig. 22(a) except that two pairs of bipolar electrodes 350a  
17 and 350b are used. Fig. 25(a) shows the electrodes 350(a) and  
18 350(b) extending outward from sheaths 348(a) and 348(b) at the  
19 distal end 349. Electrodes 350(a) are preferably either both  
20 active or both passive, while the pair of electrodes 350b  
21 encased in sheaths 348b have the opposite polarity.  
22 Alternatively, the electrodes can have cross-polarity. The  
23 configuration shown in Fig. 25(a) creates an approximately  
24 square or rectangular pattern of electrodes (depending upon  
25 spacing of 350a and 350b). The sheaths and electrodes are  
26 shown bent at an angle of approximately 90 degrees, but other  
27 angles are useful as well, and are included in the spirit of  
28 the invention. Although four sheath and electrode pairs are  
29 described with two as preferably receiving the active  
30 voltage/power and the other two as ground, or i.e. passive,  
31 various other combinations are possible and included in the  
32 invention. A few of these possibilities are illustrated  
33 through use of Figs. 25(b) - 25(f) which show views of the  
34 ends of the sheaths and electrodes, omitting other details for  
35 clarity. For example, Fig. 25(b) illustrates the arrangement  
36 of electrodes in Fig. 25(a). With electrodes 350(a) active  
37 and 350(b) passive, electric fields will extend between the  
38 two pairs approximately as shown by the dotted lines. The

1 tissue will be heated in a volume having a cross section which  
2 can be seen to be an approximate square or rectangular,  
3 depending on the spacing of the electrodes. The pattern for  
4 two electrodes (i.e. a bipolar electrode) is shown in Fig.  
5 25(c). The volume of tissue ablation is controlled by the  
6 depth of insertion of the needle electrodes into the tissue.

7 Another alternative is shown in Fig. 25(d) in which two  
8 passive electrodes 350a are used with a third active electrode  
9 350b, resulting in a generally circular cross sectional area  
10 of tissue ablation. Use of more electrodes will provide a  
11 more circular cross-section. As examples, Figs. 25(e) and  
12 25(f) are further variations which result in circular tissue  
13 ablation, both utilizing an active electrode 350b surrounded  
14 by passive electrodes 350a. In all of the above described  
15 configurations, energy is passed from one electrode or  
16 electrodes to another electrode or electrodes, through tissue  
17 in between, causing it to be heated. The preferred number of  
18 passive electrodes for circular tissue coagulation is in the  
19 range from 3 up to a maximum of 16. For optimal distribution  
20 of energy from the electrodes, it is preferred that the sum  
21 of areas of the active electrodes (designated as 350b in Fig.  
22 25) be approximately equal to the sum of the areas of the  
23 passive electrode(s) 350a.

24 Fig. 26 shows an embodiment of the present invention  
25 providing a circular zone of coagulation of adjustable  
26 diameter. Active electrode 350b is surrounded in a circular  
27 pattern by passive electrodes 352. Electrodes 352 are  
28 superelastic metal "memory wires" such as nickel-titanium  
29 wires which are pre-tensioned to a bowed shape or angle.  
30 While the electrodes are inside of tubes 354, they are held  
31 in straight position. When the electrodes are advanced  
32 outside of tubes 354, they angle outward from the central axis  
33 of the supporting tube 354. Electrode 350b is straight and  
34 preferably carries the active energy from the RF power source.  
35 In operation, the electrodes 352 and 350b are all connected  
36 to the electrode moving mechanism 236 (Fig. 20) and moved in  
37 and out together. Alternately, electrode 350b may be  
38 independently moved relative to the other electrodes 352, thus



1 allowing for significant flexibility in adjusting the area of  
2 ablation or coagulation. For clarity of illustration, only  
3 a portion of the tubes and electrodes is shown. The assembly  
4 is shown cut off at 355, but actually extends in length, the  
5 electrodes 352 and 350b having a proximal end (not shown)  
6 which connects to the electrode moving mechanism, which in  
7 turn connects the electrodes to an RF energy source, for  
8 transmitting the power to the distal ends at 353. The dashed  
9 lines in Fig. 26(a) illustrate the movement of electrodes 350b  
10 and 352, the central electrode 350b being coaxial with the  
11 central axis and preferably extending or retracting  
12 independently of electrodes 352. As shown by the dashed  
13 lines, electrodes 352 may be extended outward and away from  
14 electrode 350b, the greater extension providing a greater  
15 cross-section of ablation/coagulation. The end of central  
16 electrode 350b is extended into the same plane as the ends of  
17 electrodes 352 for coagulation of a volume of tissue having  
18 a circular cross sectional area.

19 Use of superelastic "memory wires" which exit the tubes  
20 354 at predetermined angles is preferred. Another method of  
21 angling the electrodes outward is more clearly shown in Fig.  
22 26(b) illustrating one of the tubes 354 with an electrode 352  
23 installed therein. The pre-induced angle of electrode 352  
24 causes it to bear against the interior wall 356 and the rim  
25 358 of the opening 360. The structure of tube 354 and  
26 electrode 352 combination (as shown in the figure) requires  
27 tube 354 to be constructed of an electrically insulating  
28 material since no coating is shown on electrode 352.  
29 Alternatively, or in addition to having tube 354 non-  
30 conductive, the electrode wires can be insulated with a thin  
31 non-conductive coating except for the end portion of the  
32 wires. In this manner, the only active portions of the  
33 electrodes are those portions which do not have the non-  
34 conductive coating.

35 Fig. 26(a) shows a grouping of six tubes enclosing  
36 electrodes 352, and one tube with an electrode 350b. Although  
37 six tubes 354 are shown, the invention also includes other  
38 numbers of tubes, electrodes, and configurations, including

1 such configurations corresponding to the patterns illustrated  
2 in Figs. 25(b) to 25(f). Arrangement of electrodes in a  
3 different pattern can be done to obtain coagulation of a  
4 volume of tissue having a rectangular, circular or other cross  
5 section. As an alternate construction, the tubes 354 and 362  
6 could be merged in one continuous piece of material with the  
7 required bores for guiding the electrodes formed therethrough.  
8 Such an embodiment would look similar to the cylindrical  
9 section of the embodiment to be described in Fig. 27. Note  
10 that the further the electrodes are advanced out of the tubes  
11 into body tissue, the greater will be the volume of tissue  
12 coagulated, as the tissue provides a conductive path for the  
13 RF energy along the lengths of the electrodes inserted in the  
14 tissue.

15 Referring now to Fig. 27, there is shown an alternate  
16 embodiment for accomplishing a similar purpose as presented  
17 in regard to the embodiment of Fig. 26. Instead of angular  
18 memory wire electrodes, all of electrodes 366 are straight,  
19 and preferably constructed of superelastic conductive  
20 material, such as nickel titanium wire. Electrodes 366 as  
21 well as central electrode 368 are all guided by holes 370  
22 through the first section 372 of the guiding structure 373.  
23 The structure 373 has a conical shaped end section 374, the  
24 narrow end of which is connected to a first end face 376 from  
25 which electrodes 366 emerge, and extends from the face 376 to  
26 a wide end 378 from which the central electrode 368 emerges.  
27 The conical shape 374 interferes with the electrodes 366,  
28 deflecting them outward from the central axis 375 away from  
29 the central electrode 368. This provides a method for varying  
30 the angle of deflection from the central axis, and thereby  
31 achieving a larger or smaller cross section of tissue  
32 coagulation, with end sections using different angles for the  
33 conical shape.

34 As with the embodiment of Fig. 26, the further the  
35 electrodes 366 are protruded from the casing 372, the farther  
36 they extend from the central electrode 368, creating a larger  
37 area of ablation/coagulation. The electrodes' proximal ends

1 at 380 are to be connected to an electrode movement mechanism  
2 such as 236 shown in Fig. 20.

3 Figure 28 illustrates a connecting cable assembly 394 for  
4 an RF generator system utilizing the apparatus above  
5 described, and additionally has the facility for providing  
6 either monopolar RF power to the electrodes for tissue  
7 cutting/coagulation or bipolar power for coagulation  
8 procedures. The use of the monopolar RF power between two  
9 electrodes in close proximity has not been addressed in the  
10 prior art, and will be shown to have significant advantages.  
11 In the prior art, monopolar electrodes have been used with a  
12 patient return pad to complete the electrical path. Monopolar  
13 applications use higher RF power, typically for tissue cutting  
14 and coagulation. The use of patient return pads creates an  
15 electrical path from the active monopolar electrode to the  
16 return pad. This path therefore tends to be relatively long,  
17 unpredictable, and unsafe.

18 The single connecting cable system shown in Fig. 28  
19 allows the surgeon to use one instrument either in monopolar  
20 or bipolar mode. The single cable system also eliminates the  
21 need for patient return grounding pads and the associated risk  
22 of "stray currents" and adjacent tissue damage. In Fig. 28,  
23 cable assembly 394 includes two bipolar cables 396 and 398  
24 having banana plugs 400 and 402, each of the cables 396 and  
25 398 leading from an interconnection block 404. The banana  
26 plugs 400 and 402 are for interconnection with bipolar  
27 receptacles 406 and 408 of RF generator 410. There is a  
28 monopolar output cable 412 leading from the interconnection  
29 block 404 with a monopolar plug 414 for interconnection with  
30 monopolar receptacle 416 of the RF generator 410 (receptacle  
31 416 is typically labelled "Foot Control" in commercially  
32 available RF generators). A return path cable 418 is shown  
33 leading from the interconnection block 404, and has a  
34 connector 420 for mating with receptacle 422 of the RF  
35 generator 410 (receptacle 422 is typically labelled "Patient  
36 Return"). The function of the interconnection block is to  
37 join the bipolar cables 396 and 398 to the monopolar output  
38 cable 412 and return path cable 418. The block 404 then

1 connects the resultant two wires to an output cable 424 which  
2 passes the RF power through a connector assembly 425 to  
3 electrode movement mechanism 236 which in turn connects the  
4 power to the electrodes.

5 The RF generator 410 is a standard energy source in the  
6 industry, and has facility for switching the power output  
7 either to the higher power level for use in the monopolar mode  
8 for cut/coagulation, or to the lower power bipolar mode for  
9 coagulation. Fig. 28 also shows a standard foot pedal 426  
10 interconnected with the RF power generator 410 through cable  
11 428 for turning the RF power output of the generator 410 off  
12 or on in cut or coagulation mode.

13 The above described cable assembly is used with the above  
14 described endoscopic surgical instrument to allow either  
15 monopolar or bipolar power to be supplied to the electrodes  
16 without having to manually connect and disconnect separate  
17 cables to RF generator 410.

18 The convenience of being able to select either monopolar  
19 or a bipolar energy for application to a single electrode  
20 assembly gives a surgeon significantly enhanced surgical  
21 capability and convenience. In the monopolar mode, ablation  
22 and removal of tissue is possible, and in the bipolar mode,  
23 coagulation is possible, allowing the surgeon to make  
24 decisions after insertion of a single electrode apparatus.  
25 Previously, use of electrodes in bipolar and monopolar modes  
26 required time consuming removal of electrodes and complete  
27 change of operating procedures and instrumentation.

28

#### 29 Method For Removing Uterine Fibroids

30 Over thirty percent of women between 30 and 50 years of  
31 age have uterine fibroids, which can cause abnormal bleeding  
32 and associated problems. There are three major kinds of  
33 fibroids: (1) subserosal fibroids which are located outside  
34 the wall of the uterus; (2) intramural fibroids which are  
35 located inside the uterine wall; and (3) submucosal fibroids  
36 which are located outside the endometrium. The majority of  
37 fibroids needing treatment to prevent abnormal bleeding are  
38 the submucosal type. Treatment options for uterine fibroids

1 have included drug therapy and surgical treatment. Drug  
2 therapy is used to shrink the fibroid, but is expensive and  
3 fibroids return to their original size within four months of  
4 ceasing use of the drug therapy. Surgical treatment such as  
5 myomectomy or hysterectomy involve significant hospital stay  
6 and recovery time as well as high costs. Alternative  
7 treatments therefore are preferred to drug therapy or surgical  
8 treatment.

9 Laparoscopic myoma coagulation is used for the treatment  
10 of subserosal and intramural fibroids. Submucosal fibroids  
11 cannot be treated laparoscopically due to the need for an  
12 internal incision and closure of the uterine wall.  
13 Laparoscopic coagulation uses a Nd:YAG laser or  
14 bipolar/monopolar electrosurgical electrodes to shrink the  
15 fibroids.

16 The prior art use of R.F. needle electrodes for  
17 laparoscopic coagulation has been limited to a single  
18 monopolar electrode or to a pair of bipolar electrodes for  
19 laparoscopic treatment of uterine fibroids because the prior  
20 art electrodes can only be used along the axis of  
21 visualization of the laparoscope. Additionally, the prior  
22 art single monopolar or pair of bipolar electrodes have  
23 provided only a limited area of tissue coagulation. The  
24 electrodes of the present invention as described above,  
25 provide a larger zone of coagulation, and may be used for  
26 laparoscopic or hysteroscopic treatment of uterine fibroids.  
27 The needle electrodes described herein may be introduced to  
28 the sidewall of the uterus at any angle to the axis of  
29 visualization of the hysteroscope.

30 The flexible needle electrodes of the present invention  
31 allow the angle of entry to tissue (relative to the axis of  
32 the probe) to be adjusted to any angle. Moreover, the use of  
33 multiple electrodes with an adjustable angle of entry to  
34 tissue, allows a larger sized area of tissue coagulation,  
35 including areas which have greater area than the size of the  
36 probe which guides the needle electrodes to the tissue  
37 insertion site.

1           The present invention treats uterine fibroids with  
2 hysteroscopic myolysis. The uterine fibroids are first  
3 identified using hysteroscopy, endovaginal ultrasound,  
4 computerized axial tomography, or MRI to allow visualization  
5 of the interior of the uterine cavity. By such imaging of the  
6 uterine cavity, the size, shape and position of any fibroid  
7 can be determined. Hysteroscopic myolysis can then be  
8 performed using a monopolar needle electrode, or one of the  
9 bipolar needle electrode configurations of the present  
10 invention as above described. To protect the rectum, bladder  
11 and blood vessels of the uterus, vaginal ultrasound is used  
12 to determine the fibroid's posterior surface prior to  
13 insertion of the electrode(s). The R.F. needle electrodes are  
14 then inserted through an operating hysteroscope. The  
15 electrodes can then be manipulated and inserted in the  
16 fibroids to the desired depth under direct visualization of  
17 the hysteroscope, and the area surrounding the electrodes may  
18 be coagulated. By repeatedly puncturing the fibroid with the  
19 needle electrodes, the entire fibroid can be coagulated.

20           This disclosure addresses uterine fibroid treatment in  
21 particular. However, the method described can be used for  
22 ablation/removal of any soft tissue, such as breast, liver,  
23 colon, and prostate tumors/growths.

24           Although the present invention has been described above  
25 in terms of a specific embodiment, it is anticipated that  
26 alterations and modifications thereof will no doubt become  
27 apparent to those skilled in the art. It is therefore  
28 intended that the following claims be interpreted as covering  
29 all such alterations and modifications as fall within the true  
30 spirit and scope of the invention.

What is claimed is:

CLAIMS

1        1.     A cable connecting system for use with an endoscopic  
2        surgical instrument having RF electrode means, said system  
3        connecting said electrode means to an RF energy source capable  
4        of generating monopolar and bipolar RF energy, the connecting  
5        system comprising:        means for connecting the monopolar  
6        RF output to the RF electrode means and means for connecting  
7        the bipolar RF output to the RF electrode means, whereby the  
8        electrode means may be used in either bipolar or monopolar  
9        mode by selecting bipolar or monopolar RF energy from the RF  
10       energy source.

1        2.     An RF electrode assembly for ablating a body tissue  
2        portion, comprising:

3            (a)    at least three electrodes arranged in a non-linear  
4        pattern and disposed in an insulating unit;

5            (b)    electrode movement means, whereby said electrodes  
6        may be advanced out of said insulating unit into said body  
7        tissue portion, thereby providing an adjustable volume of  
8        tissue ablation when RF energy is passed through said  
9        electrodes.

1        3.     The assembly of claim 2, wherein one or more of said  
2        electrodes exit said insulating unit to provide a cross-  
3        section of tissue ablation greater in size than the cross-  
4        section of said unit.

1        4.     A method for soft tissue ablation/removal, comprising:

2            (a)    directing an endoscopic instrument including RF  
3        electrode means to the target tissue;

4            (b)    advancing said RF electrode means into said tissue,  
5        said electrode means comprising at least three electrodes  
6        arranged in a non-linear pattern to engage a volume of tissue  
7        between said electrodes;

8           (c) providing RF energy to said electrodes, thereby  
9           ablating/removing said tissue.



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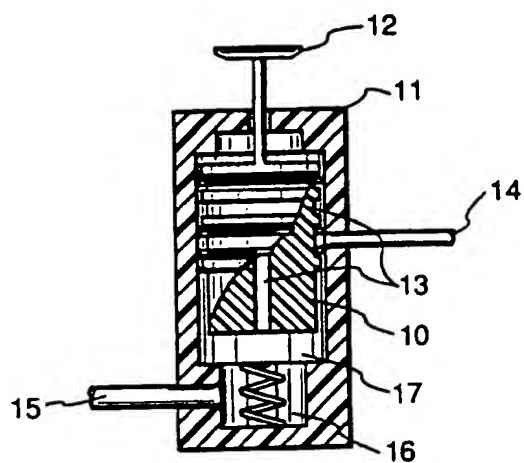


Fig. 1

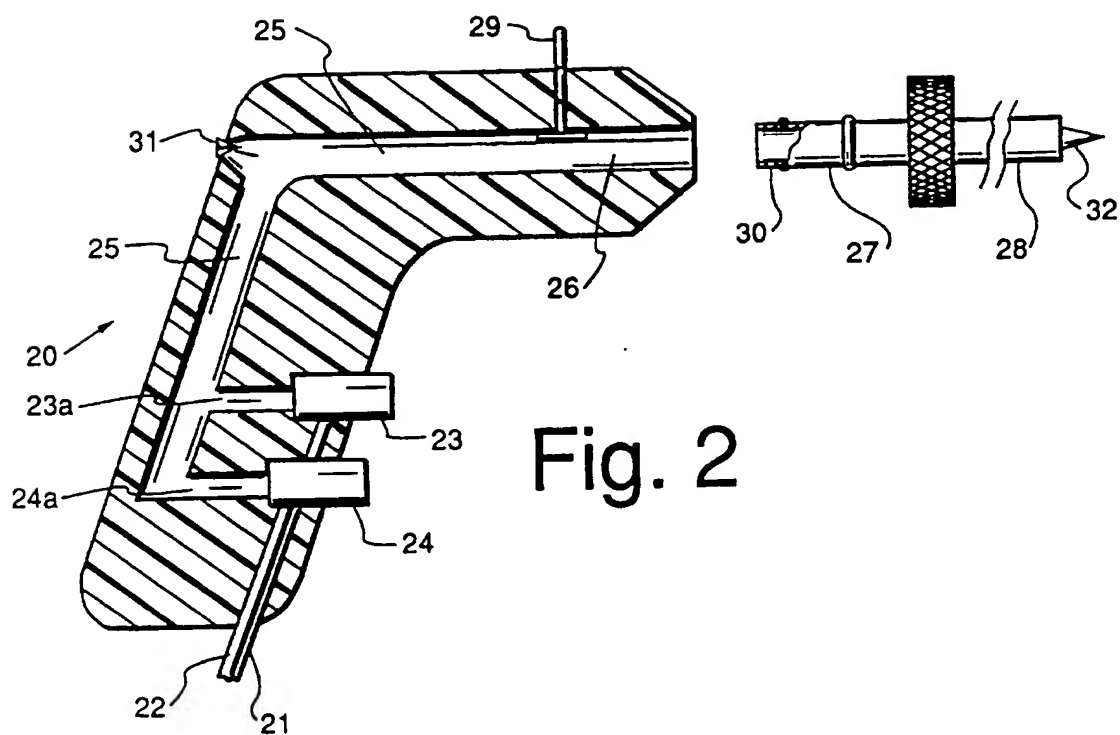


Fig. 2

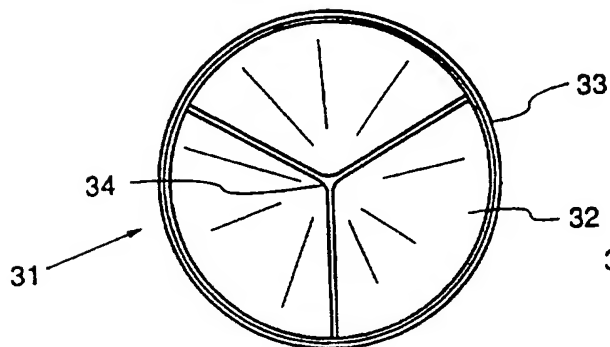


Fig. 3a

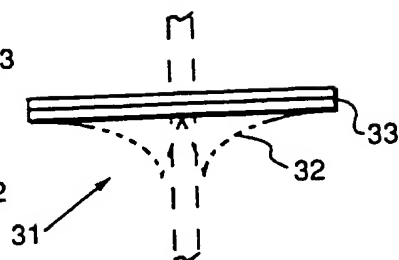


Fig. 3b

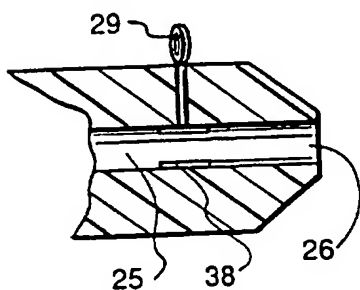


Fig. 4a

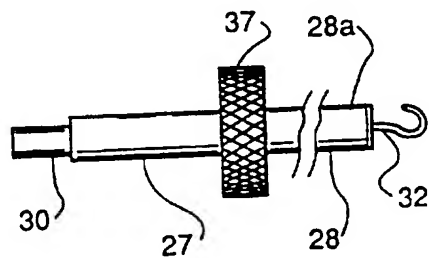


Fig. 4b

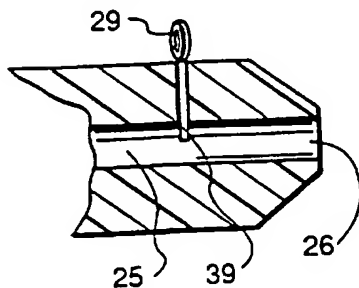


Fig. 5a

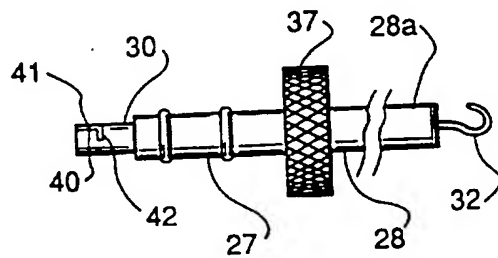
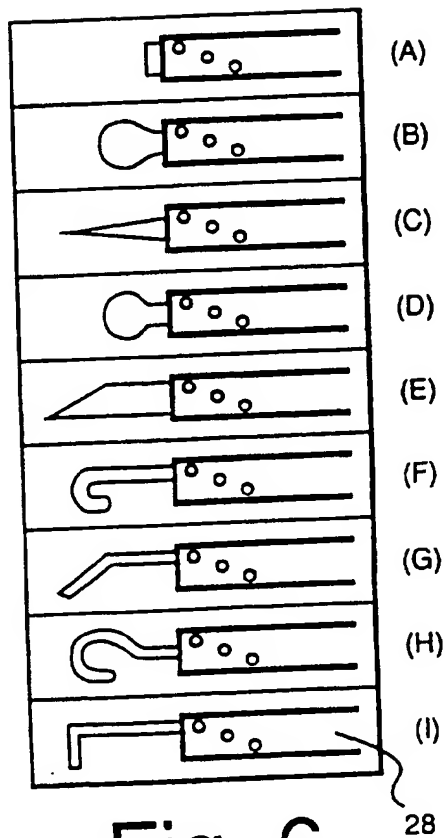
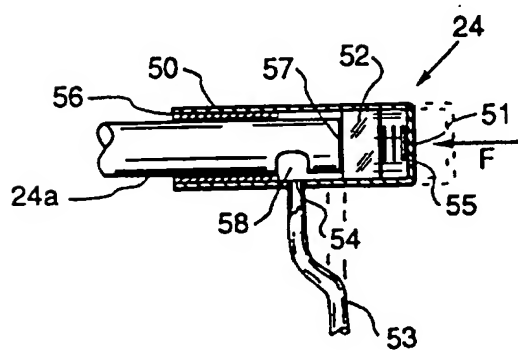
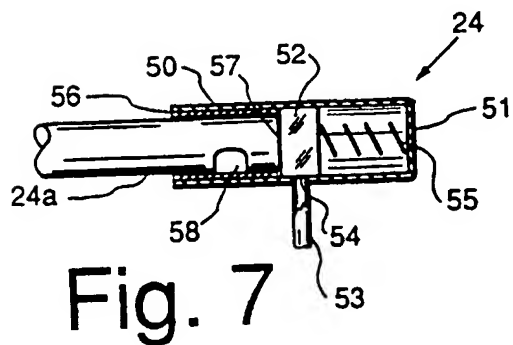


Fig. 5b



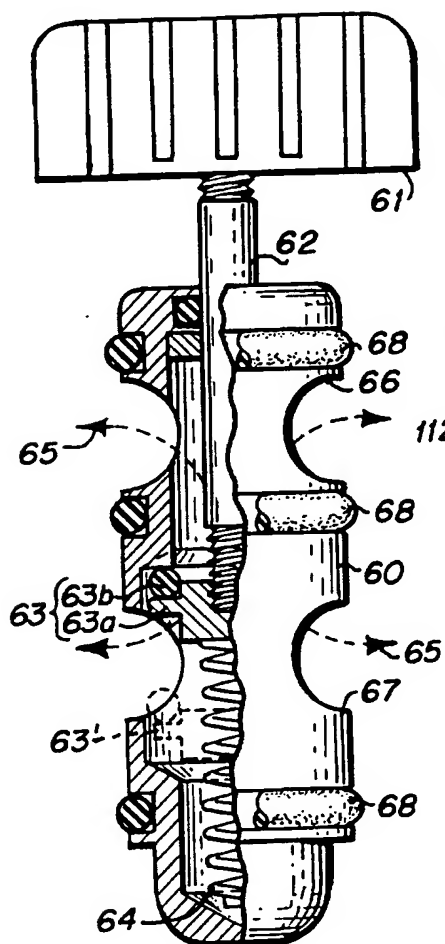


Fig. 9

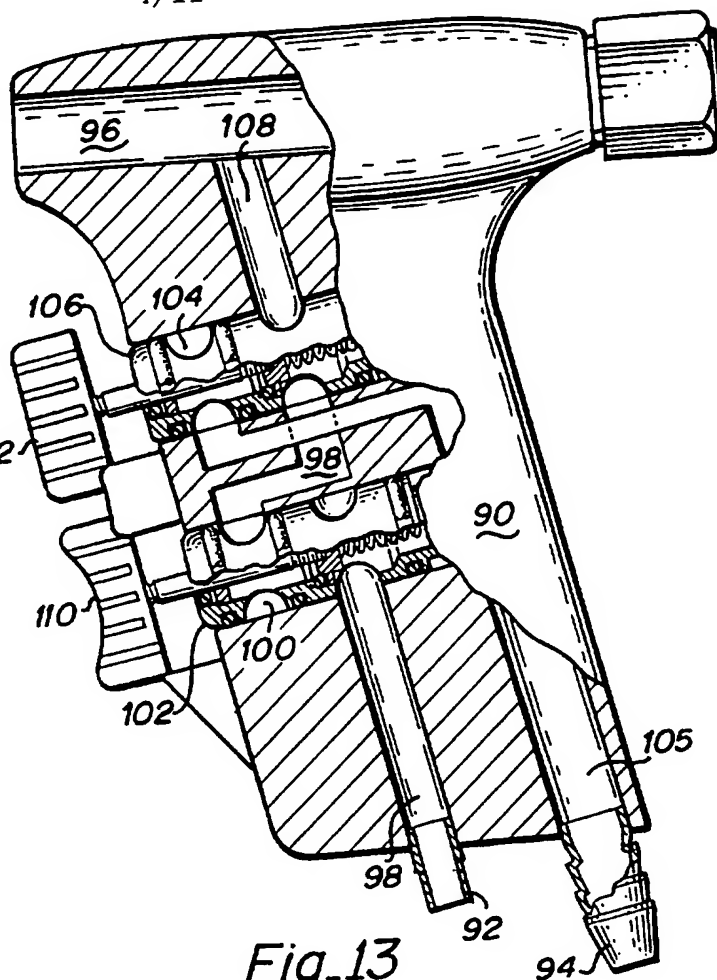


Fig. 13

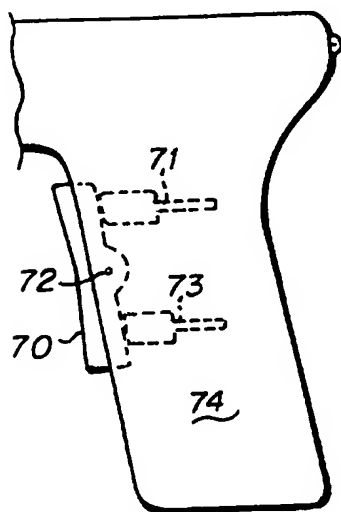


Fig. 10

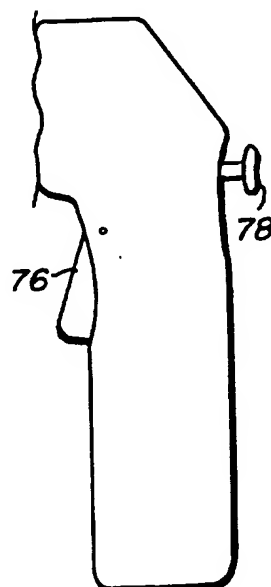


Fig. 11

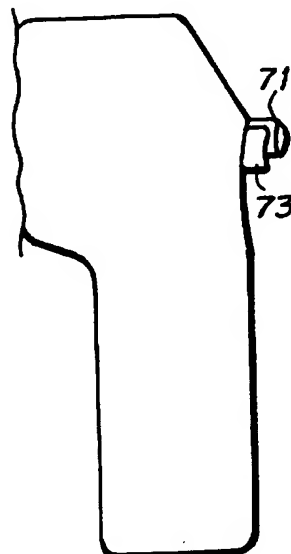
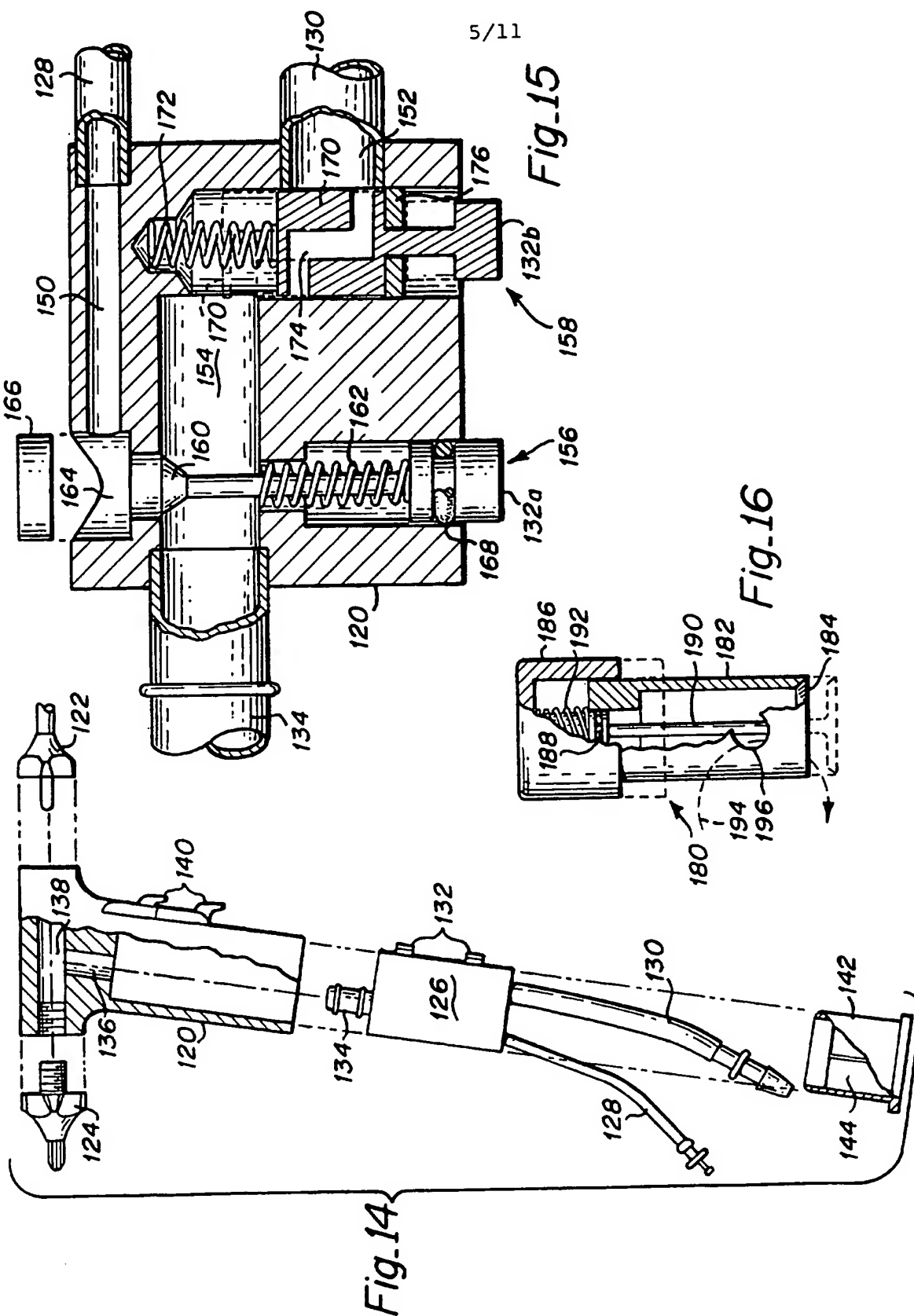


Fig. 12



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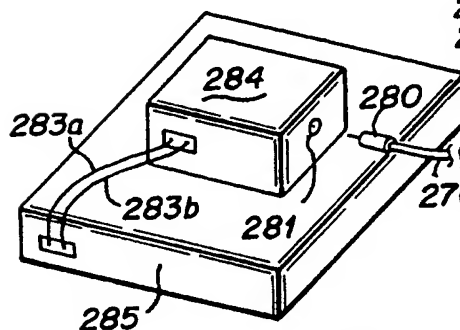
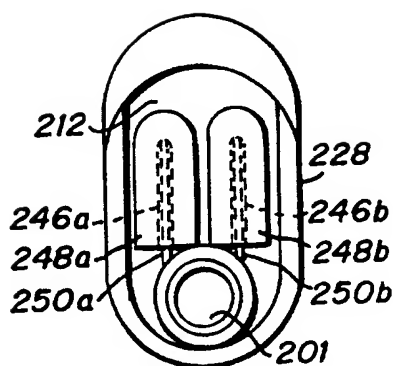
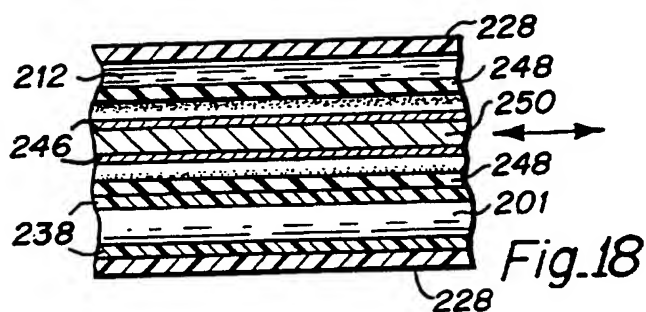
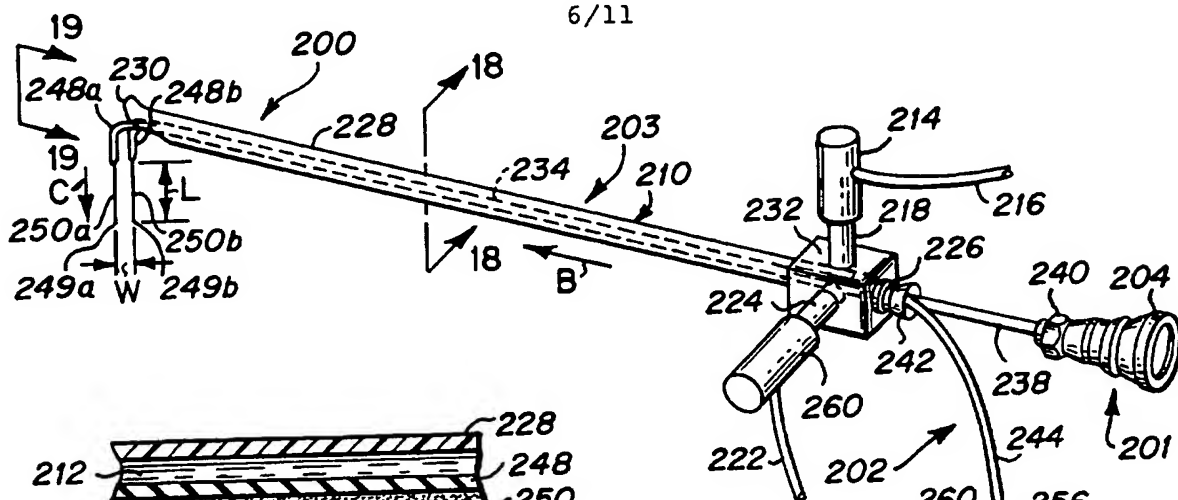


Fig. 19

Fig. 20

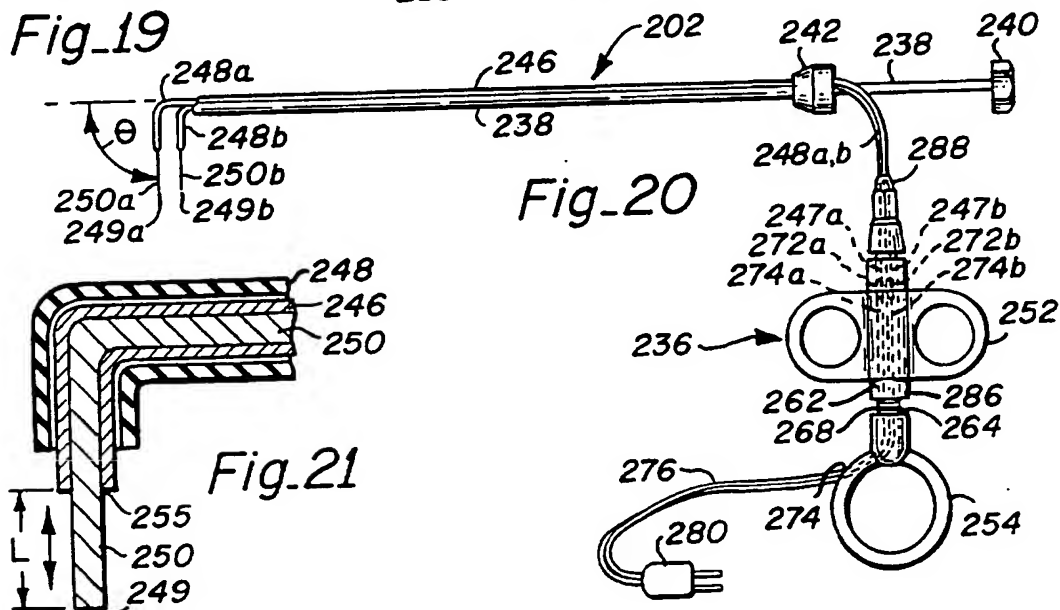


Fig. 21

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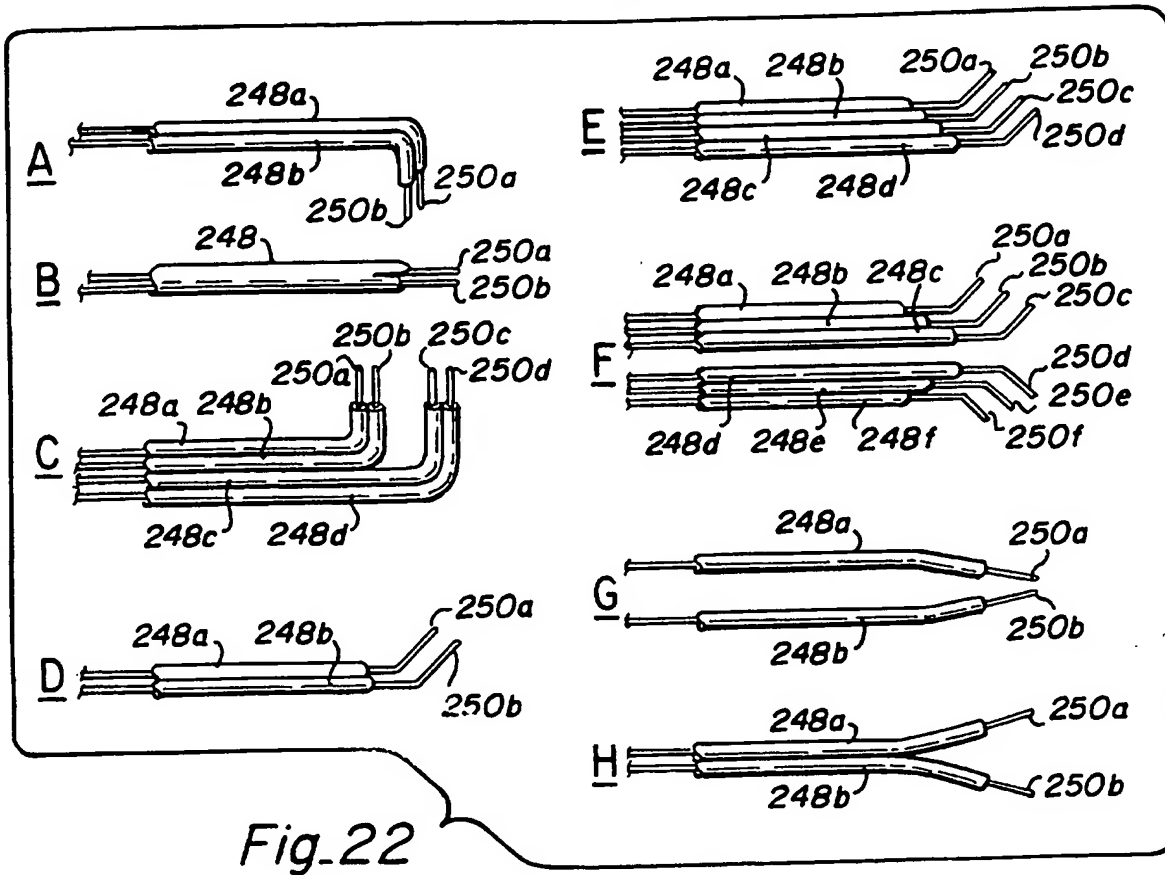


Fig. 22

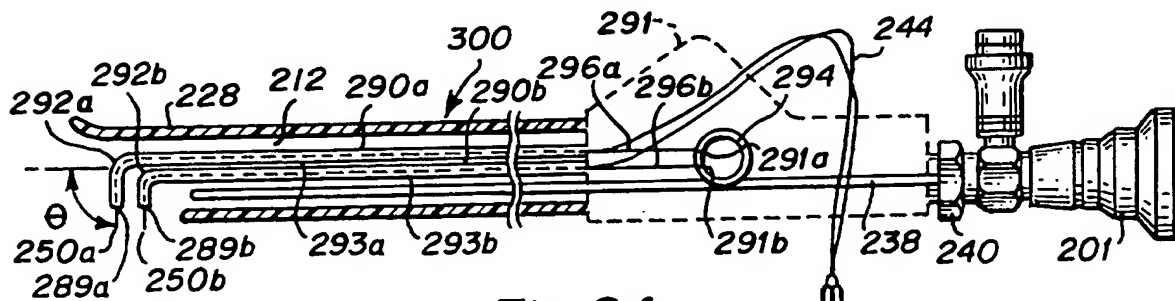


Fig. 24

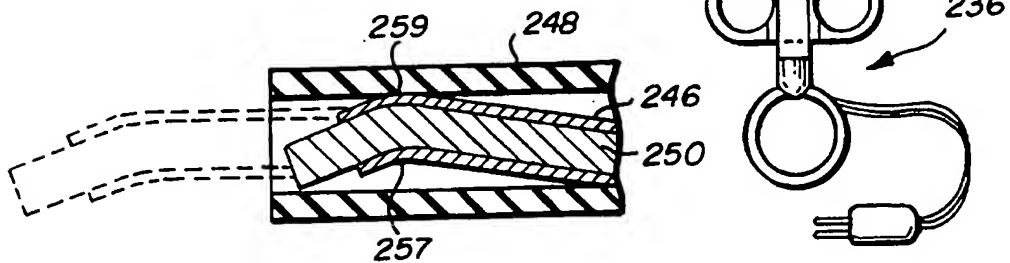


Fig. 23

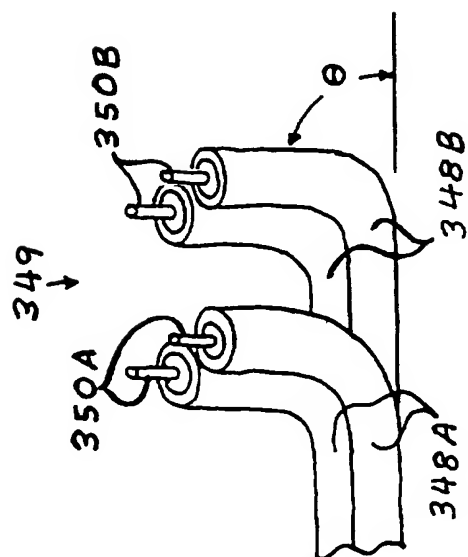


FIG 25A

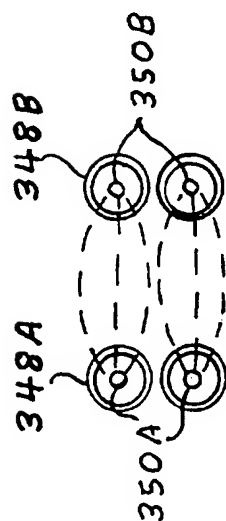


FIG 25B

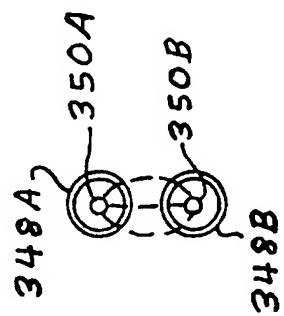


FIG 25C

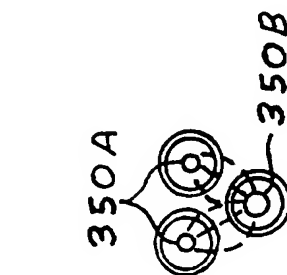


FIG 25D

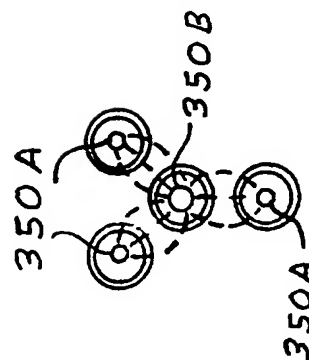


FIG 25E

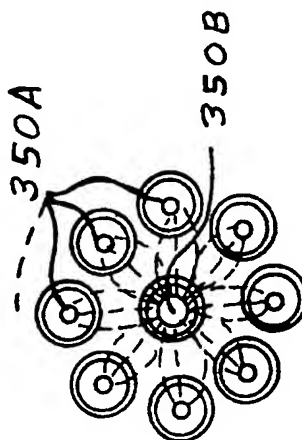
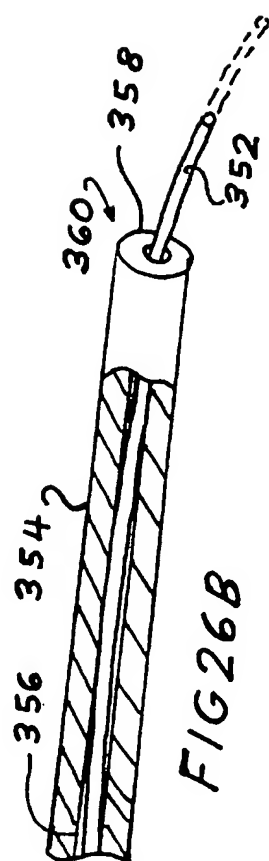
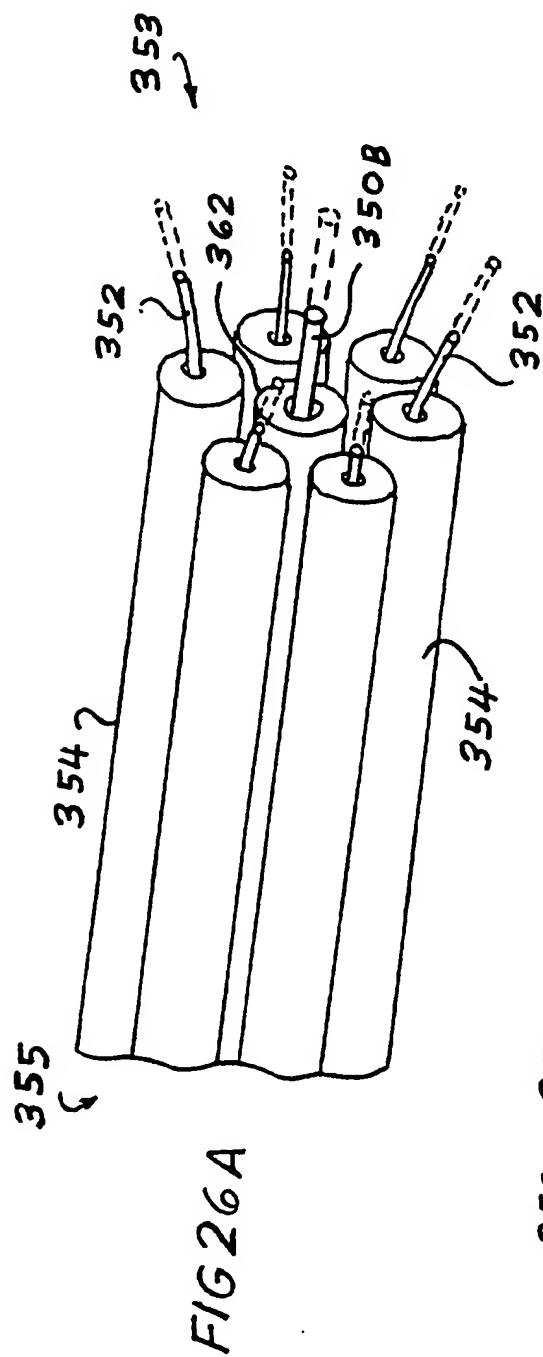


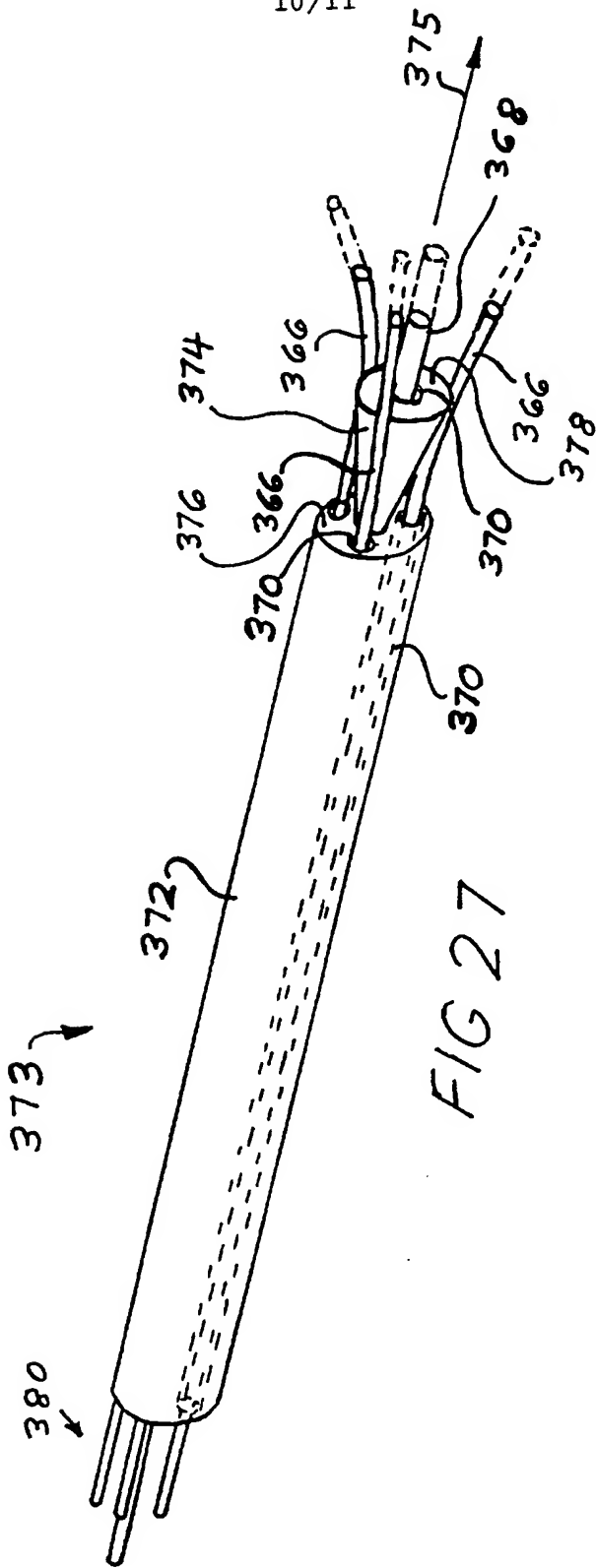
FIG 25F



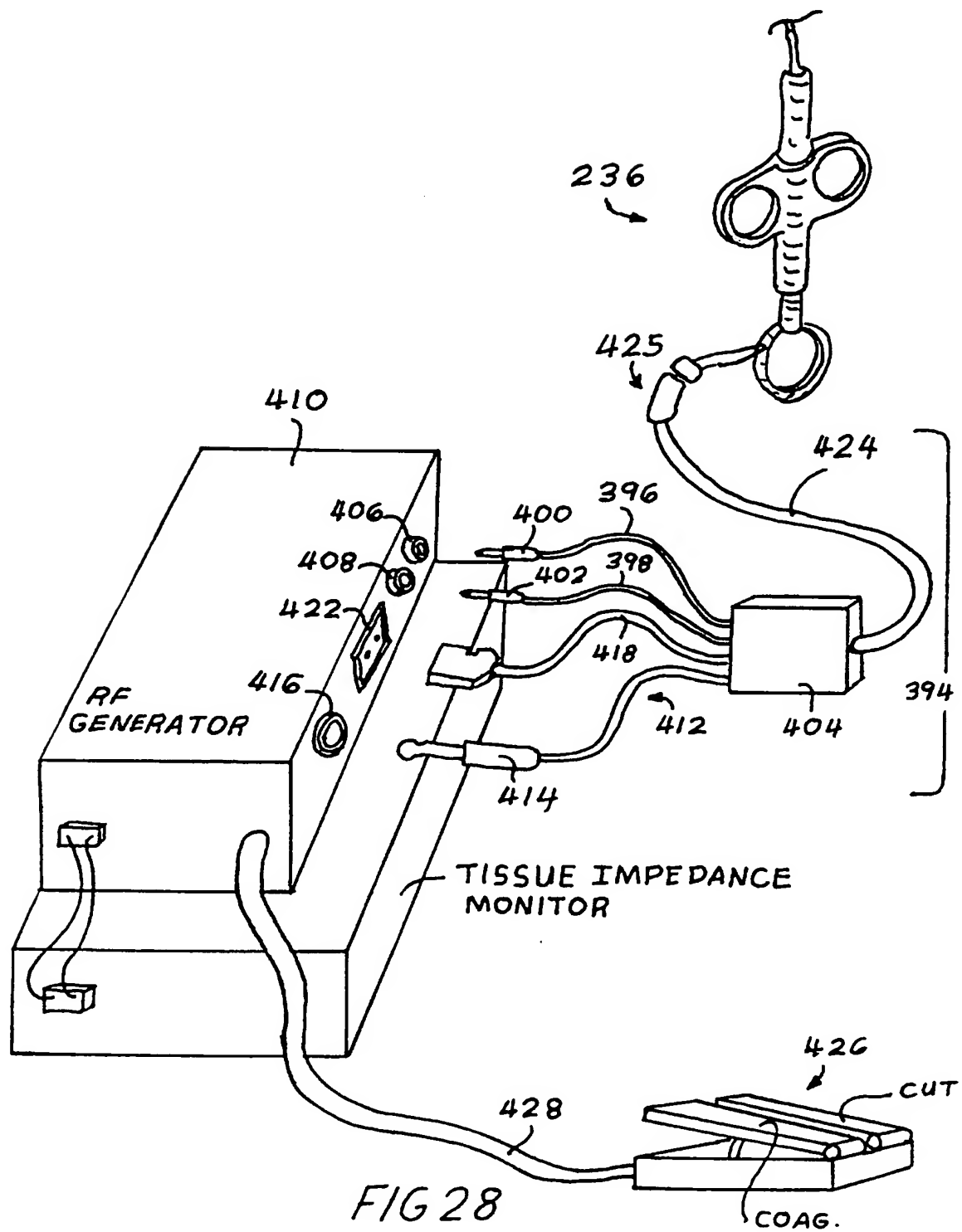
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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US95/13892

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/50

US CL : 606/210

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/27, 30, 32-35, 167, 294, 904; 606/39-41, 45, 45, 210

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,186,714 (BOUDREAU ET AL.) 16 February 1993, see the entire document.	1-4
A	US, A, 4,402,310 (KIMURA) 06 September 1983, see the entire document.	1-4



Further documents are listed in the continuation of Box C.



See patent family annex.

\*

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document defining the general state of the art which is not considered to be part of particular relevance

\*E\*

earlier document published on or after the international filing date

\*L\*

document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\*

document referring to an oral disclosure, use, exhibition or other means

\*P\*

document published prior to the international filing date but later than the priority date claimed

\*T\*

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\*

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\*

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

\*Z\*

document member of the same patent family

Date of the actual completion of the international search

19 FEBRUARY 1996

Date of mailing of the international search report

08 MAR 1996

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Authorized officer

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**INTERNATIONAL SEARCH REPORT**International application No.  
PCT/US94/12477**C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 3,994,287, (TURP ET AL.), 30 November 1976. See entire document.	13-15
A	US, A, 4,573,448, (KAMBIN), 04 March 1986. See entire document.	13-15
A	US, A, 4,815,467, (CHESTNUT), 28 March 1989. See entire document.	13-15

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